Percutaneous Needle Fasciotomy for Dupuytren's Disease: Report on a Randomized Clinical Trial and Related Research

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Lay-out: Roos van Vugt-Heeringa
Printing: GVO drukkers & vormgevers BV te Ede

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Financial support for printing this dissertation was obtained by kind contributions from Afdeling Platische Chirurgie UMCG, Allergan, BlooMEDical, Junior Vereniging Plastische Chirurgie, Maatschap Plastische, Reconstructieve en Hand Chirurgie Isala Klinieken, Nederlandse Vereniging voor Plastische Chirurgie, Pfizer BV, Zwols Wetenschapsfonds Isala Klinieken

ISBN: 978-90-9026677-0

RIJKSUNIVERSITEIT GRONINGEN

Percutaneous Needle Fasciotomy for Dupuytren's Disease: Report on a Randomized Clinical Trial and Related Research

Proefschrift

ter verkrijging van het doctoraat in de
Medische Wetenschappen
aan de Rijksuniversiteit Groningen
op gezag van de
Rector Magnificus, dr. E. Sterken,
in het openbaar te verdedigen op
woensdag 23 mei 2012
om 12.45 uur

door

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geboren op 25 juni 1980
te Alkmaar

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ISBN: 978-90-9026677-0

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CHAPTER ONE:

INTRODUCTION AND OUTLINE OF THIS THESIS

INTRODUCTION

Dupuytren's Disease is a fibromatosis of the palmar fascias of the hand and fingers, which often leads to extension deficit. Patients may develop problems using their hands in daily activities. The cause is not yet fully elucidated. It seems however, that smoking, excessive alcohol consumption, male gender, diabetes mellitus, epilepsy and possibly performing heavy manual labor increase the chances of getting the disease (Leclercq 2000, Abe 2004). Dupuytren's Disease is most common among Caucasians living in or originating from North-West Europe. The prevalence in a country is strongly influenced by the study parameters and varies from 0.2 to 56% (Ross 1999, Wilbrand 1999, Gudmundsson 2000, Thurston 2003, Zerajic 2004, Hindocha 2006, Degreef 2010). Especially men aged 50 years and over are affected but as age progresses, the prevalence among women increases to a 1:1 ratio in the ninth decade of life (Anthony 2008). There is a familial predisposition, suggesting a genetic origin. The complete genetic profile of Dupuytren's Disease is not yet fully unraveled (Rehman et al, 2008, Hindocha et al 2006, Bayat et al, 2003), but work from a consortium of Dupuytren study groups from the UK, Germany and initiated and coordinated in Groningen, The Netherlands, has recently revealed nine susceptibility loci and a role for the WNT-signalling pathway in the pathogenesis of the disease (Dolmans et al. 2011).

DIAGNOSIS

Dupuytren's Disease is a clinical diagnosis that can be made easily in most cases. However, the first manifestations of DD may cause very subtle irregularities in the palm, which can be confused with other diseases, even by an experienced clinician. When the nodules start to grow and appear in the distal palm or the base of the finger, it becomes easier to diagnose. In the initial phase, the nodules may be painful when compressed, but this sign usually disappears with time. Skin pits are the earliest signs of contraction of some of the affected fibers as is blanching of the skin during extension. Nevertheless, the differential diagnosis of Dupuytren's Disease in this stage still is extensive: ganglion and inclusion cysts, occupational hyperkeratosis,

callous formation, tenosynovitis, giant cell tumours, and epitheloid sarcoma have to be ruled out (Rayan 1999). Once the disease progresses, cords start to appear. By the time contractures emerge, the diagnosis of Dupuytren's disease is hard to miss, although the differential diagnosis of dermal contracture as in burns, bowstringing following damage to the pulley system, flexor tendon adhesions and intrinsic joint contractures should be considered.

The area around the distal interphalangeal joint (DIP joint) is rarely affected and flexion deformities there are scarce, but a Boutonniere deformity may develop. Dupuytren's sequelae are usually located on the ulnar side of the hand and the fourth digit is mostly affected (James et al, 1952). Dupuytren's Disease is often not only restricted to the fascia, but also the surrounding subcutaneous tissue and the skin can be involved (Meyerding et al, 1941).

Associated fibromatoses, also referred to as ectopic lesions, are Peyronie's disease (fibromatosis of the tunica albuginea), which may lead to a curvature of the penis in erection, and Ledderhose's Disease (plantar fibromatosis), which implies the formation of nodules in the plantar fascia which may cause walking problems. Besides, in patients with DD sometimes nodules appear on the dorsum of the PIP-joints: Garrod's knuckle pads.

PROGNOSIS

The number of treatment options for Dupuytren's Disease has increased in the last decades, but research into their effectiveness with high levels of evidence is limited. There is at present no cure for Dupuytren's Disease, and Dupuytren's Disease should be regarded as a chronic illness. Therefore, in most cases after treatment, new pathological tissue is formed in the previously operated field and besides; extension of the disease into new locations is inevitable. Both events often lead to new contractures. There are risk factors that have been suggested to influence the time of occurrence and severity of recurrence. Hueston was the first to coin the term diathesis for high-risk patients (Hueston 1984).

The risk of recurrence is higher if the first signs of the disease occur before the age of 40, if close relatives are affected or if ectopic lesions are present (Hindocha 2006). Bilateral disease, radial involvement and fifth digit involvement have been named as other risk factors for a more aggressive disease course (Abe et al., 2004). Moreover each treatment gives its own specific risk for recurrence. All these factors together determine the disease course; this should be taken into consideration when counselling a patient and proposing a treatment option.

TREATMENT OPTIONS

Treatment options can be divided into either surgical or non-surgical. Surgical procedures in their turn can be subdivided into minimally invasive and invasive procedures. Among the many options, which will all be described in detail in Chapter 2, two of the most commonly performed surgical treatment modalities are limited fasciectomy, and percutaneous needle fasciotomy. In most countries, including the Netherlands, limited fasciectomy is the most frequently practiced treatment for Dupuytren's Disease. Percutaneous needle fasciotomy is a less invasive technique that has been reinvented and has gained increasing popularity n the last decades among others due to its shorter recovery period.

Limited Fasciectomy

In limited fasciectomy, after elevation of the skin preferably in a plane between healthy skin and subcutis on one hand and the fibromatosis on the other, all macroscopically abnormal tissues are excised while care is taken to preserve the neurovascular bundles and the tendon sheet. There is global consensus that intervention is indicated for progressing contractures of at least 30˚ in one of the joints. The treatment should preferably be performed before a contracture of 60˚ has developed. A contracture of > 60˚, especially in the PIP joint, is more difficult to correct, because it may be accompanied by shortening of the check rein and collateral ligaments, and attenuation of the central extensor slip, which makes durable correction very difficult (Smith &Breed 1994).

As the thickening and shortening can displace the neurovascular bundles, these could be damaged during the intervention. This complication is reported in 0-2% of the patients during the first surgical intervention and up to 10% of patients if a recurrence is treated (Coert et al., 2006). The total cumulative risk for complications is reported in 3.6% - 39.1% of cases, but apart from damage of the neurovascular bundle most other complications can be treated conservatively, an example being minor wound healing issues (Clibbon et al., 2001, McFarlane and McGrouther 1990, Denkler 2010).
A major disadvantage of limited fasciectomy is that on average it takes 6 weeks before the patient has regained full use of the treated hand and some hands remain stiff after treatment.
Recurrence rates after fasciectomy differ enormously, from 2-73% (McFarlane 1990, Jurisic 2008). However, the reader of the literature on Dupuytren's Disease should realise that "recurrence" is an ill-defined entity. During the course of this study we were once again confronted with the fact that this makes comparison between studies almost impossible.

Percutaneous needle fasciotomy or aponeurotomy

At the end of the seventies of the previous century a group of French rheumatologists revived and refined the original method of treatment of fasciotomy suggested by Henry Cline of London in 1777 (Cline 1777). This was originally an open transsection of pathological cords. In the current practise the affected cords are weakened or cut percutaneously under local anesthesia with the help of an injection needle.
In experienced hands the cumulative risk for complications was found to be lower in needle fasciotomy than in limited fasciectomy (Badois 1993). Adverse events included skin breaks (20 hands, 16% of cases), digital dysesthesia due to nerve damage (3 patients, 2% of cases), and local infection (3 patients, 2% of cases) (Badois 1993).
Because of its minimal invasiveness, limited amount of complications and quick functional recovery, the intervention is seen by some as a panacea for the treatment of Dupuytren's Disease and has gained great popularity among patients on different Internet forums (for websites, the reader is referred to References 14, 15, 16).
Long-term follow up studies on PNF are scarce. However, from those available it can be concluded that a major drawback is early recurrence with a cumulative rate of 58% after three years in a study of Foucher and of 50% after 5 years in a study by Badois (Foucher 2003, Badois 1993).

It should be noted again that Badois used an ill-defined definition of recurrence. Moreover, it is currently unknown how effective PNF is as a treatment for recurrent disease, and there are no reports available on its long-term outcome in the treatment of recurrence. It is possible that PNF, although hampered by a higher recurrence rate than LF, can postpone a more invasive treatment, such as dermofasciectomy or limited fasciectomy.

Limited fasciectomy versus percutanous needle fasciotomy

The ideal treatment for Dupuytren's disease is one, which is easy and quick to perform, causes little treatment burden, has little risk of complications and a fast recovery of function, and a long disease-free period. Needle fasciotomy is elegant because of its minimally invasive character, and seems to meet many of the criteria, although recurrence rates seem high. Limited fasciectomy has for long served well as standard treatment, but the major drawback is a prolonged recovery.

Definitions of treatment outcome and recurrence rates

To compare outcomes in treatment regimens for Dupuytren's disease, it is essential that information about the success of different surgical approaches be presented in the same way in all studies. This also accounts for recurrence rates.
Comparison for LF and PNF on the basis of the medical literature is difficult if not impossible. This is first of all due to the fact that research on percutaneous needle fasciotomy is limited to date. Another problem is the fact that one of the major outcome parameters, "recurrence", is used for very diverse conditions in literature. The most commonly used definition, "reappearance of Dupuytren's tissue in a previously operated zone" (Mc Farlane & McGrouther 1990), cannot be used in percutaneous needle fasciotomy, since in PNF no tissue is removed.

AIMS OF THIS THESIS

The main aim of this thesis was to study the short-term efficacy and recovery pattern, and complication rates, and the medium (3 yrs) and long-term (5 yrs) recurrence rates of percutaneous needle fasciotomy (PNF) for Dupuytren's disease, and compare the treatment modality on these items to limited fasciectomy (LF) in a randomised clinical trial. To this aim an extensive study protocol was designed in concordance with the Dutch Law for scientific research on Humans (WMO) and approved in January 2002 (protocol number 02.0107). The trial was registered at ISRCTN, registration number ISRCTN 58554745. In addition, and with the aim to fill a knowledge gap, we investigated the effectiveness and outcome of PNF as a treatment modality for recurrent disease and its long-term outcome.

OUTLINE OF THIS THESIS

Chapter 2 gives a full overview of all currently available treatment options for Dupuytren's Disease; a review of the medical literature was performed to illustrate all treatment modalities with their pro's and con's.

Before embarking on the RCT, a pilot study was performed to investigate if our results of percutaneous needle fasciotomy were comparable to those of others who have reported on this technique. The results of this pilot study will be presented in **Chapter 3**.

Chapters 4, 5 and 6 are devoted to the randomized clinical trial that compares LF and PNF.
In **chapter 4**, the patient population of the RCT will be presented together with the randomisation procedure, the details of the treatments employed, all pre- and post-operative assessment tools and the immediate and 6 weeks results of our randomised controlled study, including the complications of limited fasciectomy and percutaneous needle fasciotomy. The primary outcome parameter is total passive extension deficit (TPED) reduction and secondary outcome parameters are complication rate, patient's satisfaction and hand function recovery as investigated by DASH.

Chapter 5 reports on the intermediate, 3-years follow-up results. This study focuses primarily on recurrence figures and their comparison to data available in the literature.

Chapter 6 encompasses the study of the 5-year postoperative results of both treatment modalities and compares those also to the recurrence figures from studies using collagenase. Besides it investigates if Dupuytren's diathesis and other demographics influence the risk of recurrent disease. It also reports on satisfaction of patients and their preference for subsequent treatment – if desired.

Chapter 7 describes the effectiveness and long-term outcome of PNF for recurrent Dupuytren's disease.

Chapter 8 describes a literature study, designed to list definitions and rates of contracture correction and recurrence in patients undergoing surgical treatment of Dupuytren's contracture. This study was done to make future meaningful comparison of results achieved with different surgical interventions possible.

Chapter 9 summarizes the conclusions that can be drawn from this thesis and provides a general discussion of the complete work.

Chapter 10 is a Dutch translation of Chapter 9.

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CHAPTER TWO:

TREATMENT OF DUPUYTREN'S DISEASE, AN OVERVIEW OF OPTIONS

This chapter has in extended form been published as:

Van Rijssen A.L., Werker P.M.N. Ned Tijdschr Geneeskd. 2009;153:A129.

&

Van Rijssen A.L. and Werker, P.M.N. In: Charles Eaton, M. Heinrich Seegenschmiedt, Ardeshir Bayat, Giulio Gabbiani, Paul Werker, Wolfgang Wach, editors. Dupuytren's Disease and Related Hyperproliferative Disorders- Principles, Research, and Clinical Perspectives. Springer, 2012; 35-43

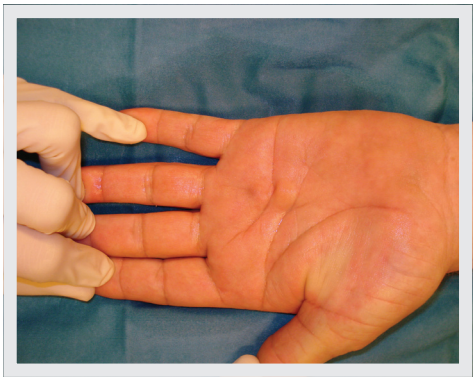
ABSTRACT

In this chapter we present a systematic overview of the current treatment options for Dupuytren's Disease. Few publications on the effectiveness of these treatment options provide greater than level 4 evidence (expert opinion). Most hand surgeons practice limited fasciectomy. Dermofasciectomy is used for the treatment of recurrences due to the reported lower risk of recurrence. Percutaneous needle fasciotomy is a minimally invasive technique with good results in the short term for mild contractures, but has a high recurrence rate. Collagenase has been introduced to the American market and short-term results are promising. Some, but not all, have reported that radiotherapy delays disease progression if applied in early stages of the disease.

INTRODUCTION

Dupuytren's Disease (DD) is a fibromatosis of the palmer fascia of the hand and fingers, which often leads to flexion deformity of especially the ulnar fingers. Patients with digital contracture from DD may develop difficulty using their hands in daily activities (Figures 1 and 2).

Figure 1: A patient with the initial stages of Dupuytren's Disease.



The fingers can still be fully extended, but in the hand palm at the level of the fourth ray a nodule and skin pitting are visible.

Figure 2: The hand of a patient with Dupuytren's Disease.

There is a contracture in the proximal interphalangeal joint of the fifth ray. The distal interphalangeal joint shows compensatory hyperextension, a Boutonniere deformity.

There is no cure for Dupuytren's Disease, neither can it be prevented. After treatment, the disease may recur in the previously operated field or extend to a new location. There are risk factors that influence the timing and severity of recurrence. The risk of recurrence is higher if the onset of the disease is before the age of 50, if the disease occurs in close relatives or if ectopic lesions are present on the dorsum of the PIP joint (knuckle pads, Garrod's pads), the penis (Peyronie's Disease) or the foot (Ledderhose Disease). Bilateral disease, radial involvement and small finger involvement are other known risk factors (Abe et al. 2004). There are different treatment options for Dupuytren's Disease, but high-level evidence of their effectiveness is limited.

Each treatment has its own specific risk for recurrence. All these factors together determine the prognosis; this should be taken into consideration when counselling a patient and proposing a treatment option.

In this chapter we give an overview of the different treatment options with the best available evidence (level 3 or greater).

LITERATURE ANALYSIS

We have analysed the existing literature, using Medline and the Cochrane Library without date limit. The search terms were "Dupuytren's Disease", "Morbus Dupuytren", "Dupuytren", "fasciectomy", "fasciotomy", "aponeurotomy", "radiotherapy AND Dupuytren", "splinting AND Dupuytren" and "post operative hand therapy". For subsequent analysis we used only the relevant articles or abstracts in English, French or German. The relevance of an article was determined by the title or abstract. We found one relevant systematic review, nine relevant randomized clinical trials and nine case-control studies. Due to this limited number of studies, we also included the cohort studies that reported on more than 100 cases. An overview of the treatments with their advantages and disadvantages is summarized in Table 1. In the analysis we followed the usual classification of levels of evidence desgined by the Centre of Evidence Based Medicine:

- Level 1: At least 1 systematic review or 2 randomized clinical comparative studies conducted independent from each other.
- Level 2: At least 2 independently conducted studies (randomized clinical trials of moderate quality of insufficient size) or other comparative studies (non randomized comparative cohort study or case- control study)
- Level 3: At least one study of level 2 or a non comparative study
- Level 4: Expert opinion

Table 1: Overview of the treatments for Dupuytren's Disease, including results and recurrence risks

Treatment	Indication	Results	Complications	Recurrence	Disadvantages	Level of evi-
Limited fasciectomy (Clibbon 2001, Foucher 1992, McCash 1964,)	>30° contracture, painful nodules (Clibbon 2001, Foucher 1992, McCash 1964,)		Hematoma, skin necrosis, neurovascular damage (Clibbon 2001, McCash 1964)	41% in 5 years (Foucher 1992)	Invasive treatment. Complications in 19% of patients. 6 weeks of rehabilitation (Clibbon 2001, McFarlane 1990)	Level 3
Dermofasciectomy (Armstrong 2000, Ketchum 2011)	Recurrences. Aggressive disease in patients younger than 40	Comparable to limited fasciectomy.	Hematoma, loss of skin graft, infection, neurovascular damage	8.4% after 6 years	Most invasive treatment, further disadvantages same as with limited fasciectomy + those of skin grafting	Level 3
Percutaneous needle fasciotomy (Badois 1992, Foucher 1992, 2001)	Stage I disease with isolated and moderate flexion at the metacarpo-phalangeal (MP) level (Foucher)	81% good or excellent (Tubiana classification ≤ 1) (Badois 1993) immediate improvement of 76% (Foucher 2001)	skin breaks (4-16%), digital nerve damage (0,4-2%), local infection (0-2%). (Badois 1993, Foucher 2001)	58% after 3.2 years	"Blind technique" high recurrence rate.	Level 3
Clostridial Collagenase (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010)	Contracture associated with a palpable cord (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010)	87% success (correction within 0-5° of full extension) (Badalamente 2002, 2007, Hurst 2009, Watt 2010)	Local, temporary reaction to injection (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010)	19% after 2 years. (Hurst 2009,Watt 2010)	Not tested sufficiently for safety and effectiveness for general use in EU, not selective for diseased tissue	Level 2
Radiotherapy (Adamietz, 2001, Betz 2010, Falter 1991, Keilholz 1997, Seegenschmiedt 2001, Weinzierl 1993)	Disease in initial phase (Adamietz, 2001, Betz 2010, Falter 1991, Keilholz 1997, Seegenschmiedt 2001)	Delay of progression of disease (<5 years) (Adamietz, 2001, Betz 2010, Falter 1991, Keilholz 1997, Seegenschmiedt 2001)	Erythema and other skin conditions, long term damage (Falter 1991)	Mixed results: delay of development of contractures in stage N and Tubiana I, vs. no difference between treated and non treated patients after 7 years. (Weinzierl 1993)	Only suitable in early stage	Level 3

SURGICAL TREATMENT

Limited Fasciectomy

In most countries limited fasciectomy is the most frequently practiced treatment for Dupuytren's Disease. Only abnormal tissues are excised while care is taken to preserve unaffected fascia and neurovascular bundles (figure 3).

Figure 3: Surgical treatment of Dupuytren's Contracture.

The fibrotic tissue that caused the contracture has been removed via a zigzag Bruner incision in the finger and palm.

Indications: This intervention is indicated for painful nodules that do not respond to conservative measures (padded gloves) or for progressing contractures of at least 30˚ in one of the joints. The treatment should preferably be performed before a contracture of 60˚ has developed. PIP joint contracture greater than 60˚ is more difficult to correct, because it may be accompanied by contracture of the checkrein and collateral ligaments (Misra et al. 2007) and by lengthening of the extensor mechanism (Smith and Breed 1994).

Disadvantages: As the thickening and shortening can displace the neurovascular bundles, these could be damaged during the intervention. This complication rate is reported in 0-2% of the patients during the first surgical intervention and up to 10% of patients in recurrent cases. The total cumulative risk for complications is 19% whereby we note that apart from damage of the neurovascular bundle most other complications are minor such as wound healing issues (Clibbon et al., 2001, McFarlane and McGrouther 1990). The probability of recurrence after limited fasciectomy is 41% within 5 years (Foucher et al, 1992). Recurrence rates differ enormously, from 2-73% (McFarlane 1990, Jurisic 2008). Another disadvantage of limited fasciectomy is that on average it takes 6 weeks before the patient can use the treated hand again fully.

Segmental Fasciectomy

In Belgium, Moermans popularized segmental fasciectomy. In this operation 1 cm segments of the diseased fascia are removed. The authors found decreased morbidity, quicker recovery but similar recurrence rates, when comparing their results to those reported in the literature (Moermans 1996).

Radical Fasciectomy

Radical fasciectomy, popular in the 1950s and early 1960s, fell out of favour because of a high incidence of complications and is mentioned for historical purposes (Chick 1991). In radical fasciectomy, the fascia is widely removed but the overlying skin is preserved. Incisions may vary, but the operation usually is completed by the redistribution of elevated skin in such a way that most of the wound can be closed.

Open Palm Technique

Some advocate leaving the skin in the palm over the transverse ligament of the palmar aponeurosis open to allow for wound drainage (McCash, 1964). This technique has been found to have less complications but a slightly extended duration until complete wound healing.

Dermofasciectomy

Dermofasciectomy is a method where, together with the affected fascia, the overlying skin is excised. A skin graft is used to cover the skin defect. This method is indicated for patients who have either a high risk for recurrence or a recurrence with skin involvement. The rationale for the use of dermofasciectomy comes from a cohort study on 143 digits, where the skin was removed in the area between the distal palmer crease and the PIP joint. The risk of recurrence after this radical method was only 8.4% after 5,8 years (Armstrong et al, 2000). Similar satisfactory results with a shorter follow have been presented as well (Ketchum 2011). However, in this technique the skin grafts were used as fire breaks placed in transverse incisions. In addition to the disadvantages of fasciectomy there are also the disadvantages that are associated with harvesting and application of a skin graft.

Percutaneous needle fasciotomy or aponeurotomy

In the 1970s, a group of French rheumatologists revived and modified the original method of treatment developed by Henry Cline of London in 1777 (Cline 1777). With percutaneous needle fasciotomy (PNF), the affected cords are weakened or cut under local anesthesia with the help of an injection needle (Figure 4).

Figure 4a and b: The hand of a patient with Dupuytren's Contracture before and after treatment with percutaneous needle fasciotomy.

A palmar cord can be seen at the level of the fifth ray (Fig a). The contracture is mainly in the metacarpal phalangeal joint. The contracture was cut with a needle in several places (black lines in Fig .b). Following treatment, the finger is straight. (Courtesy: H. ter Linden).

Indications. This technique has recently gained wide popularity. It is a minimally invasive intervention, with a brief recovery period. The first results of this technique were published in 1980 by Lermusiaux and Debeyre (1980). In the 1990s, Badois et al. (1993) and Foucher et al. (2001) presented their long-term results of needle fasciotomy, the latter only using lignocaine and needle fasciotomy, without steroid injection. Badois et al. (1993) performed percutaneous needle fasciotomy on 138 patients and found that 81% of the treated hands had good or excellent primary results, defined as a Tubiana classification ≤ 1 or a residual TPED of less than 45°. In the group of patients with Tubiana Stage IV disease pre-operatively, 48% had good results. Foucher and his colleagues reported an immediate improvement of 72% in their 1998 study and 76% in their 2001 study, which included some of the patients of the first study (Foucher et al., 1998, 2001).

Disadvantages. Despite the advantages in the short term, this intervention also has clear disadvantages. Long term follow-up of showed that the recurrence rate after needle fasciotomy is much higher than after limited fasciectomy. Foucher et al. (2001) reviewed 100 rays treated by percutaneous needle fasciotomy after a mean of 3.2 years. Fifty-eight per cent showed signs of recurrence.

For patients with likelihood for high recurrence rate this treatment seems not to be the best treatment option.

NON-SURGICAL TREATMENT

Injections

Many non-surgical interventions have been tried out, but so far none have replaced surgical treatment.

Human enzymes

From the beginning of the 20th century it has been tried to dissolve the thickened fascia various agents including pepsin, trypsin, hyaluronidase and thiosinamin (Langemak, 1907). As the effects of these agents were very brief, they were abandoned. Only one study in our review has been done on enzymatic fasciotomy other than collagenase. This was a cohort study (evidence level 3) of only 10 treated hands in 9 patients injected with a mixture of lignocaine, trypsin and hyaluronidase, with a follow up of 6.5 years. After 2 to 3 years 7 patients again had a contracture with similar severity as before the treatment (McCarthy 1992).

Corticosteroids

The results of the use of local injections with corticosteroids are contradictory (Baxter et al. 1952, Ketchum and Donahue 2000). At best, painful nodules without contractures may become less symptomatic following local depot corticosteroid injection (Badalemente and Hurst 2000, Ketchum and Donahue 2000).

Clostridial Collagenase

In the last few years, studies have been published on the use of collagenase. (Badalemente and Hurst, 2007, Hurst et al. 2009). Some of these have been conducted on the safety and efficacy of collagenase, including a double blind randomized trial comparing the drug to placebo (evidence level 2) (Hurst 2009). Another study, in which thirty-three patients were treated with collagenase or with a placebo also investigated recurrences (Hurst 2007). In 87% of the therapy group the treatment was successful and the contracture disappeared completely. Nineteen percent had a recurrence within 2 years. There was no effect measured in the control group.

As of this writing, this treatment is FDA-approved in the United States and in Europe the drug is being tested in selected centres in a phase 3 trial. The treatment might be very risky in inexperienced hands because collagenase does not differentiate between normal and abnormal tissues: Clostridial collagenase acts on types 1 and 3 collagen, which are found not only in affected fibrotic cords but also tendons and retinacular fibres. Nerves have different collagen subtypes (types 2, 16, 28) (Hart 2011) and as such are resistant to Clostridial collagenase.

Radiotherapy

Indications. The largest experience with radiotherapy for Dupuytren's comes from Germany. Several studies have reported that local radiotherapy delays the development of contractures in patients who only have nodules or an extension deficit of less than 10˚ (Seegenschmiedt et al. 2001, Falter et al. 2001, Betz et al., 2010). However, a retrospective cohort study reported no difference in contracture between radiated and non-radiated hands (Weinzierl et al. 1993).

Disadvantages. The disadvantages of this treatment are well known. Radiotherapy is potentially harmful and the side effects vary from relatively harmless erythema and dry skin to carcinogenic effects in the long run (Falter et al. 1991). The risk of adverse effects is dose-dependent. Chronic toxicity events occurred in 16% (15/95) of hands treated with 30 Gy of radiation and 11% (11/103) of hands treated with 21 Gy at 3-month follow-up (Seegenschmiedt 2001). Another study reports 31.7% minor long term changes due to toxicity (Betz 2010).

An added disadvantage is the induction of fibrosis, which may increase risk of later wound healing problems. Randomized clinical trials comparing radiotherapy with controls are missing and necessary to fully disclose the potential of this treatment modality, as some of the outcome following radiotherapy might be the natural progression of early stage disease.

SPLINTING

The benefit of preoperative use of splints to prevent contractures has proved to be of no use. Postoperative splinting is controversial and the rationale for this only comes from expert opinion, the lowest level of evidence (Rives et al. 1992, Evans et al. 2002, Larson and Jerosch-Hold 2008). At the moment a large randomized trial on the effects of post-operative splinting is under way. An outline of the results will be presented in a book on Dupuytren's Disease which will be available later this year (Jerosch-Herold et al. 2011).

CONCLUSIONS

There is a wide range of treatment options for patients with Dupuytren's contracture. These options have not been compared to each other extensively. While counselling patients, one should give a realistic picture of the advantages and disadvantages of the different treatment options. The ideal treatment is one, which is quick to perform, has little risk of complications; allows early recovery of function with the least possible co-morbidity, and the longest possible disease-free period. A specialist who has experience in different techniques is the best to advise the patient. We believe that limited fasciectomy still is the gold-standard treatment. Needle fasciotomy is elegant because of the minimal invasive nature, but probably has a higher percentage of recurrence. Therefore needle fasciotomy is in our view not ideal for relatively young patients with a fast progressing Dupuytren's Contracture, although this needs to be proved by a randomized study, as not much has been published on this popular treatment.

For this group and for the patients with a recurrence, dermofasciectomy seems more appropriate, although comparative research should provide evidence for this. The role of radiotherapy and the injection of collagenase is not yet fully elucidated yet.

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CHAPTER THREE:

PERCUTANEOUS NEEDLE FASCIOTOMY IN DUPUYTREN'S DISEASE

Van Rijssen AL, Werker PMN, Journal of Hand Surgery (British and European Volume) 2006; 31B: 5: 498–501

ABSTRACT

The aim of this study was to examine our results of 74 percutaneous needle fasciotomies for Dupuytren's contracture. Pre-operative and postoperative total passive extension deficit was measured. Patients were seen at the outpatient clinic after a mean of 33 months for final follow-up. Extension deficit and sensibility were measured and flexor tendon function assessed. Recurrence, defined as an increase of the passive extension deficit of 30º or more compared to the immediate postoperative measurement, and other complications were also noted. Immediate outcome was excellent with an average improvement of 77%. After 32 months, we reviewed 55 rays. Their recurrence rate was 65%. Two patients experienced a slightly diminished sensibility on one side of the finger. There were no flexor tendon injuries. This procedure has a good short-term effect. It may be suitable for patients who want a minimally invasive treatment and to whom long-term results are less important. It may also have a place in delaying fasciectomy.

INTRODUCTION

The first treatment for Dupuytren's disease, proposed in the 18th century by Henry Cline (1777), consisted of sectioning the pathological Dupuytren's cords. This treatment, called fasciotomy or aponeurotomy, remained in use until the end of the 19th century, largely because of William Adams (1892), who used the technique routinely and wrote extensively about it up to the last decade of the 19th century. However, soon after the advent of general anaesthesia in the 1840s, Sir William Fergusson introduced treatment by excision of the diseased fascia (Fergusson, 1842) and this, increasingly, became the standard operation for this condition for the next 150 years, despite being hampered by high complication and recurrence rates. The latter have led to attempts to treat Dupuytren's disease by less-invasive alternatives, such as injection of vitamin E, splinting, radiation, physical therapy and dimethylsulfphoxide. Unfortunately, these have either proved clinically ineffective or unsuitable for clinical use (Badois et al., 1993).

Baxter et al. (1952) introduced the use of local steroid injections, but, despite initial optimism and success in softening some nodules, this has never achieved regression of actual contractures. Five years later, De Seze and Debeyre (1957) combined the injection of local steroids with splint therapy. Although they had excellent short- term results, the long-term results were not satisfactory. They then introduced the use of a needle, as a punch to weaken the cords, after injecting a mixture of prednisolone and lignocaine. Thus, the new technique of "needle fasciotomy" was born, although, if one compares the size of the bevel of a needle with the size of the blades of the bistouries knives used by Cline and his contemporaries, one realizes that this new technique was little more than a revival of Cline's technique. Because of its shorter recovery period and less invasive character, needle fasciotomy quickly gained favour with patients. The first results of this technique were published in 1980 by Lermusiaux and Debeyre (1980). In the 1990s, Badois et al. (1993) and Foucher et al. (2001) presented their long-term results of needle fasciotomy, the latter only using lignocaine and needle fasciotomy, without steroid injection.

In this article we present our experience since early 2001 with percutaneous needle fasciotomy, or PNF, following a visit in February 2001 by the senior author (PMNW) to the French rheumatologists, Drs. Thyssedou and Lermusiaux, in Paris.

PATIENTS AND METHODS

From April 2001, percutaneous needle fasciotomy was offered to all patients with primary Dupuytren's disease who had a clearly defined cord and a contracture of at least 20° at either the metacarpophalangeal (MCP) joint or at the proximal interphalangeal (PIP) joint. Only one patient in this study underwent percutaneous needle fasciotomy for contracture of the distal interphalangeal (DIP) joint. Fifty-two patients were included in this pilot study with disease of 56 hands, in which 74 rays were treated. Forty-four patients were men and 8 were women. The mean age of the patients was 65 years (SD 10). Thirty-one left and 25 right hands, including 9 middle, 29 ring and 36 little finger rays underwent percutaneous needle fasciotomy. Two rays were treated at the same operation in 16 hands and 3 rays were treated synchronously in one hand.

On initial presentation, the flexion contractures of the MCP, PIP and DIP joints of involved rays were measured. These figures were added to achieve the total passive extension deficit (TPED) of each ray and classified according to Tubiana's staging system (Tubiana, 1999) (Fig 1).

Tubiana I	= TPED of 0-45°
Tubiana II	= TPED of 45-90°
Tubiana III	= TPED of 90-135°
Tubiana IV	= TPED of $\geq 135^{o}$

TPED	= $PED_{MCP} + PED_{PIP} + PED_{DIP}$
TPED	= Total Passive Extension Deficit
PED	= Passive Extension Deficit

Fig 1: The Tubiana Classification of Dupuytren's Contracture of the Fingers.

OPERATIVE TECHNIQUE

Percutaneous needle fasciotomy was performed as described by Lermusiaux and Debeyre (1980). Patients were treated in an outpatient setting under local anaesthesia using 1ml or less of lidocaine 1% and epinephrine 1:100,000 per treatment site. After disinfection and draping, the cord responsible for the flexion contracture of the ray was sectioned at as many levels as possible in the palm and fingers, depending on the location and extent of the disease, using a 25 Gauge needle mounted on an 10ml syringe. In those cases where a soft tissue mass was present overlying the cord, in between the distal palm crease and the base of the finger, the fasciotomy in the distal part of the palm was performed with extra care to avoid nerve damage because a soft tissue mass at this site can indicate the presence of a spiral nerve (Short and Watson, 1982; Umlas et al., 1994). After division of the cord, the affected finger was passively extended to pull the ends of the sectioned cord apart and to obtain maximal release of the contracture. A small dressing was applied for 24 hours. Patients were encouraged to start flexing and extending their fingers immediately after treatment and to start using their hands normally after 24 hours. No splint was used or physiotherapy given.

All patients were seen after 1 week and the same measurements as pre-operatively were taken. Special attention was paid to identify possible complications, such as rupture of a flexor tendon, nerve damage or skin lacerations.

Patients were reviewed after 8 to 9 months post- operatively and finally, in June 2005, at a mean of 33 (SD 13) months. At this final review, 38 of the 52 patients were available for follow up. One patient had died, two patients did not want to participate further in the study, two had severe health problems and nine could not be traced. At 8 to 9 months and at final review, the same measurements were taken as pre- operatively. In addition, light touch sensitivity, tested by light stroking of each side of the fingertip, and the flexion deficit of the finger, as indicated by the distance between the pulp of the finger and the distal palmar crease during maximal active flexion, were measured. Light touch sensitivity was compared to this sensation on the other fingers of the same hand.

The diseased tissue, which is still present in the palm following percutaneous needle fasciotomy sometimes softens after the procedure and is hardly palpable. However, nodules usually remain unchanged. Because of this, the usual definition of recurrence, viz. the appearance of a new nodule or cord, cannot be used. Therefore, a recurrence was defined as a TPED increase during follow-up of 30° or more compared to the immediate postoperative measurements. This value was chosen because we recommend patients to undergo treatment in our centre when a contracture reaches 30° or more.

STATISTICS

We used the paired samples t-test for comparison of pre- operative, postoperative and follow-up measurements. The χ^2 test was used for comparing of categorical data, such as recurrence rates. For comparing the recurrence rates, we included Tubiana Stage III and Tubiana Stage IV rays in one group, because the latter contained only one digit. Significance was set at $P \leq 0.05$ (Table 1).

RESULTS

The mean pre-operative TPED was 62° (SD 31°).

Table 1: Preoperative assessment of the fingers by the Tubiana Classification

TUBIANA STAGE	Total Passive Extension Deficit	Number
	(TPED)	(n=74)
I	0-45°	28
II	45-90°	31
III	90-135°	14
IV	≥ 135°	1

TPED = Passive Extension Deficit MCP + Passive Extension Deficit PIP + Passive Extension Deficit DIP

One-week review

Mean TPED immediately after surgery was 18° (SD 26°), which was a mean reduction of TPED of 77%. The best results were obtained at the MCP joints, at which percutaneous needle fasciotomy achieved a mean reduction of TPED of 88%. The mean reduction was only 46% at the PIP joint. At the single DIP joint released in this study, percutaneous needle fasciotomy achieved a reduction of TPED of 75%. In respect of the Tubiana stages before percutaneous needle fasciotomy, there was a trend towards better results with the lower stages, but there was no significant difference between the results for different stages (Table 2).

Table 2: Immediate postoperative results of PNF at one week (n = 74)

TUBIANA STAGE	PNF	Improvement of TPED	
		%	SD
Tubiana I	28	80%	29
Tubiana II	31	78%	26
Tubiana III	14	65%	27
Tubiana IV	1	75%	
Mean improvement		77%	27

Nine-month review

After 9 months, 58 rays were available for review. Of these, the mean TPED now measured 21° (SD 25°). As the mean immediate postoperative result of these 58 rays was 19°, this deterioration was not statistically different (p = 0.349).

Final review

Fifty-five rays (74% of the original 74 rays) in 41 hands in 38 patients were available for final follow-up. Of these, 23 rays (42%) in 16 hands in 15 patients had already been treated for recurrence, 12 by percutaneous needle fasciotomy and four by selective fasciectomy after a mean of 23 (SD 14) months.

The remaining 32 treated rays in 25 hands in 23 patients were seen after a mean of 33 (SD 13) months (Table 3). The mean TPED at follow up of these 32 rays was 26° (SD 21°), which was a mean reduction of TPED of 44% from the TPED 1 week after surgery. This was a statistically significant change (P = 0.000).

Table 3: Postoperative result at final review at a mean of 33 months

TUBIANA STAGE	PNF	Improvement of TPED	
		%	SD
Tubiana I	11	41%	49
Tubiana II	19	50%	39
Tubiana III	1	92%	
Tubiana IV	1	14%	
Mean improvement		44%	

In 13 rays in 11 hands in 10 patients, the reduction of TPED was more than 30°, which we defined as recurrence. Therefore, the total recurrence rate in this series at a mean of 33 months after PNF was 36 rays. When we compared the recurrence rates for the different Tubiana stages at presentation using the χ^2 test, assuming a linear relationship between grade and recurrence, the op value was 0.18. This indicates that there was no statistical difference between the groups. The recurrence rates of the different stages are shown in Table 4.

Table 4: Recurrence rates

TUBIANA STAGE	Improvement of TPED	PNF	
	%	Recurrence	Total rays
Tubiana I	67%	16	24
Tubiana II	45%	10	22
Tubiana III and IV	89%	8	9

At first follow-up, 1 week after the operation, we noticed partial loss of sensation in one patient. The ray in which this occurred had a Stage II Tubiana contracture. At the patient's request, this finger was not explored. At final review, two patients had a reduction of flexion of 1 cm between the pulp of the treated finger and the distal palmar crease, which has not recovered up to now. However, there were no signs of flexor tendon injury. Two further patients were found to have slightly diminished light touch sensation on one side of one treated finger each at final follow-up. This had not been noted at the initial postoperative review.

DISCUSSION

Badois et al. (1993) performed percutaneous needle fasciotomy on 138 patients and found that 81% of the treated hands had good or excellent primary results, defined as a Tubiana classification ≤ 1 or a residual TPED of less than 45°. In the group of patients with Tubiana Stage IV disease pre-operatively, 48% had good results.

Bleton et al. (1997) performed a prospective study of percutaneous needle fasciotomy on 110 digits in 59 patients. Sixty-one per cent showed good results, by which these authors meant an improvement of more than 50%.

Foucher and his colleagues reported an immediate improvement of 72% in their 1998 study and 76% in their 2001 study, which included some of the patients of the first study (Foucher et al., 1998, 2001).

Immediate outcome was also very promising in our study as we achieved a reduction of 77% of the contracture in a total of 74 rays treated by percutaneous needle fasciotomy. The results were particularly good at the MCP joint, where a reduction of TPED of 88% was achieved. Results at the PIP joint were less good, with a reduction of TPED of only 46%.

Badois et al. (1993) reviewed an unknown number of rays in 123 hands, which he had treated by percutaneous needle fasciotomy and steroid injection after 5 years.

Sixty-nine percent of his patients still had good or excellent results after 5 years, defined as a Tubiana Stage I TPED, or less. Nevertheless, in his series there were 43% who had recurrences among those who originally had had Stage I disease before percutaneous needle fasciotomy and 61% who had recurrence among those who were originally in Tubiana Stage IV. The overall recurrence rate in his series was 50% although his definition of recurrence is not stated clearly in the article.

Foucher et al. (2001) reviewed 100 rays treated by percutaneous needle fasciotomy after a mean of 3.2 years. Fifty-eight per cent showed signs of recurrence.

Although our immediate outcome was very promising, the extension deficit was already starting to recur after 9 months. After 33 months, 23 (42%) of the treated rays had already undergone a second treatment for recurrence of the Dupuytren's disease while an additional 13 (23%) showed signs of recurrence. The cumulative recurrence rate of our study was 36 of 55 rays (65%) at 33 months.

Other authors have described long-term results of percutaneous fasciotomy using a scalpel, albeit defining "recurrence" a little differently in each study, which makes direct comparisons difficult. Duthie and Chesney (1997) reviewed 82 patients with 109 digits after 10 years. Only 28 (34%) had had no further surgery. In the remainder, the mean time to further surgery was 60 months.

Bryan and Ghorbal (1988) treated 44 rays and showed similar results, with a recurrence rate of 45% at 5.3 years.

From this study, we conclude that percutaneous needle fasciotomy has excellent results in the short term but recurrence occurs frequently and at a relatively early stage. Recurrence rates after other treatments of Dupuytren's disease are lower and occur later than after percutaneous needle fasciotomy. After selective fasciectomy, Foucher et al. (1992) reported a recurrence rate of 41% at 5 years and Norotte et al. (1988) reported a 71% recurrence rate at 10 years.

This leads us to the conclusion that percutaneous needle fasciotomy is suitable only for patients, such as the elderly, who want simple treatment without extensive wounds and/or functional disturbances and to achieve a good result quickly following a minimally invasive surgical insult, but for whom long-term results are less important. For others, this procedure may have a use in postponing selective fasciectomy.

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CHAPTER FOUR:

A COMPARISON OF THE DIRECT OUTCOMES OF PERCUTANEOUS NEEDLE FASCIOTOMY AND LIMITED FASCIECTOMY FOR DUPUYTREN'S DISEASE: A SIX-WEEK FOLLOW-UP STUDY

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ABSTRACT

Purpose: The demand for percutaneous needle fasciotomy (PNF) as treatment for Dupuytren's disease is increasing because of its limited invasiveness, good outcome, limited number of complications, quick recovery, and overall patient satisfaction. This randomized controlled trial was designed to test whether these short-term expectations are sound by comparing this treatment with limited fasciectomy (LF) with regard to these aspects.

Methods: We treated 166 rays: 88 by PNF and 78 by LF. Total passive extension deficit (TPED) improvement at 1 week and at 6 weeks were the primary outcome parameters; patient satisfaction, hand-function recovery, and complication rate were secondary outcome parameters. We used the Disabilities of the Arm, Shoulder, and Hand questionnaire to measure disabilities of the upper extremity before and after treatment and all adverse effects and complications were recorded.

Results: Overall TPED improvement was best at 6 weeks. In the PNF group TPED improved by 63% versus 79% in the LF group; this difference was statistically significant. Results at the proximal interphalangeal joint were worse than those at the metacarpophalangeal and distal interphalangeal joints for both the PNF and LF groups. The rays classified before surgery as Tubiana stages I and II showed no difference between these treatments, but for rays higher than stage II LF clearly was superior to PNF as a treatment modality. The rate of major complications in the LF group was 5% versus 0% in the PNF group. Patient satisfaction was almost equal but direct hand function after treatment was considered better in the PNF group, as was the degree of discomfort that patients experienced. This was underscored by the Disabilities of the Arm, Shoulder, and Hand scores in the PNF group, which were significantly lower than those in the LF group at all time points measured.

Conclusions: In the short term and in cases with a TPED of 90° or less PNF is a good treatment alternative to LF for treatment of Dupuytren's disease.

INTRODUCTION

In 1614, Felix Plater of Switzerland in his book "Observationum in hominis affectibus" was the first to describe what later became known as Dupuytren's contracture (Elliott 1988). The first treatment for this disease was described by Cline in 1777 and consisted of division of the pathologic cords (Cline 1777). The first subcutaneous fasciotomy was performed by Astley Cooper, whose name this treatment bears (Cooper's Fasciotomy) (Elliott 1988). In subsequent centuries surgical treatment regimens for Dupuytren's disease have described a complete pendulum movement: in 1834 Goyrand (Goyrand 1883), helped by the emergence of anaesthesia, performed limited fasciectomy. Gradually surgery became more aggressive reaching a summit in the 1950's, when total palmar fasciectomy was advised by McIndoe and Beare (McIndoe 1958). This treatment was hampered by a very high complication rate and therefore surgeons returned to more selective fasciectomies or LFs. In the late 1970s a group of French rheumatologists reintroduced the Cooper fasciotomy and performed it using a fine (25-gauge) needle under local anesthesia, calling it percutaneous needle fasciotomy (PNF) (Lermusiaux 1982). Some hand surgeons have adopted this technique and favorable results have been reported (Foucher 2003).

Nevertheless the technique used most frequently by hand surgeons is LF. A drawback of this procedure is a cumulative complication rate of 19% (McFarlane 1990). The most feared complication is transection of a nerve or artery, which is reported to occur in 3% of cases. Another disadvantage is the relatively long recovery period of 21 to 58 days (Rodrigo 1976, Tubiana 1999).

In contrast most patients treated by PNF can use their hands optimally within 1 week; in addition complication rates of PNF have been reported to be lower than those of LF and the complications re- ported have been less serious (Badois 1993, Bleton 1997). They consist mostly of skin tears, temporary swelling, mild hematomas, and superficial infections. A much feared major complication is the rupture of a flexor tendon, which is reported in 0.05% of cases. A reported disadvantage of PNF is the high recurrence rate of 58% after 3 years (Foucher 2003), whereas the recurrence rate of LF has been reported to be 41% after 5 years (Foucher 1992).

This study compares the short-term outcomes of PNF and LF in a randomized controlled setting. Total passive extension deficit (TPED) improvement at 1 week and 6 weeks were the primary outcome parameters and complications, patient satisfaction, and hand-function recovery were the secondary outcome parameters. (The TPED is the sum of the passive extension deficits [PEDs] of the metacarpophalangeal [MCP], proximal interphalangeal [PIP], and distal interphalangeal [DIP] joints.)

MATERIALS AND METHODS

Study Design

This study was designed according to and approved by the Medisch Ethishe Toetsings Commissie, the Dutch Medical Ethics Committee, in January 2002. Written informed consent was obtained from all patients.

Between August 2002 and January 2005 all patients with Dupuytren's disease who visited the out- patient clinics of any of the 5 plastic surgeons and 4 residents from our Department of Plastic, Reconstructive, and Hand Surgery were considered for inclusion in this trial.

Inclusion criteria were

(1) a flexion contracture of at least 30° in the MCP, PIP, or DIP joints;
(2) a clearly defined pathologic cord in the palmar fascia; and
(3) willingness to participate in this trial.

Excluded from the study were

(1) patients with postsurgical recurrence or extension of the disease,
(2) patients who were not allowed to stop taking their anticoagulants,
(3) patients generally unfit to have surgery, and
(4) patients who were not willing to participate in this study or had a specific treatment wish.

Study candidates were referred subsequently to 1 of the 2 surgeons from our department who performed this study (H.T.L. or P.M.N.W.). Patients were counseled about our study and a complete history and physical examination of both hands was performed after written informed consent had been obtained.

During the examination the amount of PED of the MCP, PIP, and DIP joints was quantified in degrees and translated into TPED and into the Tubiana classification (Table 1) (Tubiana 1999).

Table 1: The Tubiana Classification of Dupuytren's Contracture of the Fingers

Tubiana I	= TPED of 0-45°
Tubiana II	= TPED of 45-90°
Tubiana III	= TPED of 90-135°
Tubiana IV	= TPED of ≥ 135°
TPED	= PED_{MCP} + PED_{PIP} + PED_{DIP}
TPED	= Total Passive Extension Deficit
PED	= Passive Extension Deficit

The flexion deficit was recorded by measuring the distance from the distal palm crease to the pulps of the fingers while making a fist. Sensibility was tested using Semmes-Weinstein monofilaments. Furthermore the presence of knuckle pads; the presence or absence of fatty tissue between the cord and the skin distal to the distal palmar crease, indicating that the digital nerve possibly was relocated by a spiral cord; and the presence or absence of plantar or penile involvement were recorded.

Randomization

A power analysis performed beforehand based on the number of complications resulting from both treatments as previously reported dictated the inclusion of approximately 120 hands.

Patients were asked to pull a numbered envelope out of a box that had been prepared at the start of the study and that contained a note reading either "Limited Fasciectomy" or "Percutaneous Needle Fasciotomy." This determined which treatment each patient would receive. Patients who participated in this study were treated within 1 month after inclusion.

Questionnaires

Patients were asked to fill out a questionnaire about their health status and demographics and the Dutch translation of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire (Hunsaker 2002, Veehof 2002). The DASH questionnaire is a validated instrument used to score disabilities of the upper extremity during daily activities. This questionnaire consists of 30 items that address disability and symptoms of the upper extremity on a scale from 0 to 5. The scores are added and transformed into a 100-point scale. The lower the score, the less disability is experienced. The scores were completed by all patients before surgery and 1, 2, 3, 4, and 5 weeks after treatment.

Surgical Technique

All treatments were performed by the surgeons named previously in random order (H.T.L. and P.M.N.W.).

Percutaneous needle fasciotomy was performed in an outpatient treatment room in the same way as performed by Lermusiaux and Tyssedou, the French rheumatologists who were visited by the senior author (P.M.N.W.) before the commencement of the study (Lermusiaux 1980). PNF was performed in the same fashion as in a previously conducted pilot study (Van Rijssen 2006).

Patients who were allowed to interrupt the use of anticoagulants according to the guidelines given by the prescriber were asked to stop this medication. We did not determine the level of anticoagulation.

For anesthesia we used 1% lidocaine and 1:100,000 epinephrine. The cord responsible for the flexion contracture was sectioned at as many levels as possible in the palm and fingers, depending on the extent and location of the disease, with a 25-gauge needle mounted on a syringe. If fatty tissue was present between the cord and the skin fasciotomy in the distal part of the palm was performed with extra care taken to avoid a potential spiral nerve. After division of the cord the affected finger was extended passively to pull the ends of the sectioned cord apart and to obtain maximal release of the contractures. A small dressing was applied thereafter for 24 hours. Patients were encouraged to start practicing flexion and extension of the fingers immediately after treatment. No formal hand therapy was initiated.

Limited fasciectomy was performed in the surgical theater. Either regional anesthesia or general anesthesia was used according to the anesthesiologist's and patient's preferences. A tourniquet was used in all cases.
In the palm a transverse incision was performed with a longitudinal proximal extension over the cords and a distal extension toward the second and fourth web spaces as described by Skoog (Skoog 1967). In the digits a Bruner-type incision was used. After mobilization of the skin flaps all pathologic cords were excised under loupe magnification. In the palm the transverse palmar ligament was left intact. Care was taken to try to preserve all digital nerves and arteries. Adversely inflicted damage to these structures was repaired with standard microsurgical techniques. The skin was closed after transposition as necessary. In case there was a shortage of skin in the palm the transverse incision was left open. A light compressive bandage was applied and left in place for 1 week.

Patients were encouraged to start practicing flexion and extension of the fingers immediately after surgery, as soon as anesthesia had resolved. Hand therapy was not standard but was used only as needed. The stitches were removed after a minimum of 10 days.

Follow-Up

Patients were seen at the outpatient clinic 1 week and 6 weeks after treatment. During these visits the same measurements taken before surgery were taken by the surgeon using a checklist. In addition the complications of both treatments were noted.

We defined minor and major complications. Minor complications were skin fissure (small tears that sometimes occur at the site of skin penetration during PNF once a cord has been divided and the treated digit is extended) and paresthesias (tingling sensations at any part of the treated digit without objective disturbance of sensation at the tip of the digit). Major complications included infection, skin slough, hematoma, transected artery, suspected digital nerve injury, re-exploration, and suspected division of a flexor tendon.

To compare the complication rates we used these rates of minor and major complications.

We also recorded whether full flexion of the treated digits was possible at 6 weeks. Flexion was defined as reduced if a flexion deficit of 1.5 cm from the pulps to the distal palmar crease persisted.

At 1, 2, 3, 4, and 5 weeks patients were asked to fill out the DASH questionnaire. After 6 weeks patients were asked to fill out a questionnaire about treatment satisfaction. They had to give marks ranging from 0 (no/very negative) to 10 (yes/very positive).

Demographics

A total of 125 hands (121 patients) were included; 4 patients participated with both hands at separate times. From those 125 hands 2 sets of data were incomplete and 6 patients (6 hands) withdrew from the study before treatment took place. This resulted in a complete data set for 113 patients (117 hands), on whom 166 rays were treated. Eighty-eight rays were treated by PNF; 78 rays were treated by LF. In the PNF group 83 rays were affected at the MCP joint, 57 at the PIP joint, and 10 at the DIP joint. In the LF group these figures were 72, 49, and 6, respectively.

Six weeks after treatment 1 patient had died of a non–treatment-related cause and 1 set of data was lost, so there were 111 patients (115 hands) remaining.

Eighty-three percent of the patients were men. The mean age was 63 years (range, 35– 86 y). Most of our patients were Dutch; only 2 patients were from another country within northern Europe. Forty-three percent of our patients reported a positive family history for Dupuytren's disease.

The average time between acquiring the disease and the first visit to our clinic varied from 1 year to more than 20 years (average, 7 y).

Seventy percent of patients had been manual laborers during their professional lives; 41 of these had been working with their hands for more than 30 years. Thirty-four of our patients had never performed heavy labor. Fifty-nine patients stated that they used their hands intensively during their hobbies.

The groups were equal regarding the reported comorbidity, alcohol use, and other demographics (Table 2). The treated sides and rays were distributed equally over both groups.

Table 2: characteristics of patients of both the PNF Group and the LF Group

	PNF		LF		
	57 patients		56 patients		
	No.	%	No.	%	P value[b]
Gender					
Male	49	84.5%	45	81.8%	0.705
Female	9	15.5%	10	18.2%	
Dupuytren in family	23	39.7%	26	47.3%	0.075
Knuckle pads	11	19.3%	10	17.9%	0.844
Peyronie	4	7.0%	3	5.3%	0.696[b]
Ledderhose	5	8.8%	7	12.5	0.520
Epilepsy	2	3.5%	2	3.6%	0.975
Diabetes	9	15.8%	4	7.1%	0.170
Use of anticoagulants					
Platelet aggregation inhibitors	20	35.0%	9	16.1%	0.048
Coumarine derivatives	0	0%	2	3.6%	
	Mean	±SD	Mean	±SD	P value[c]
Mean age	63.9	10.6	63.6	8.9	0.855

[a] Two-tailed Chi square test

[b] Fisher's exact test

[c] Student t-test

Statistical Analysis

Statistical evaluation was performed using statistical software (SPSS software; SPSS Inc., Chicago, IL). The characteristics of both patient groups and the characteristics of the hands and digits were analyzed with cross tables.

Categorical data were analyzed with the chi-square test. If cells contained a number less than 5 we used the Fisher exact test. The rest of the data were analyzed using the Student t test. Because the data from the questionnaire were too skewed to use a t test we used a Mann-Whitney U test for analysis.

We used a t test to analyze the DASH questionnaire results. If less then 90% of the questionnaire was filled in—that is, if more than 3 of the questions were missing—by definition the score was invalid. Data for patients who did not fill out the preoperative form or more than 1 of the following questionnaires at 1, 2, 3, 4, or 5 weeks were not used in the statistical analysis.

Significance was set at a p value of less than .05.

RESULTS

Primary Outcome Parameters

Percutaneous needle fasciotomy.

The average TPED before treatment measured 66° per ray in the PNF group. The largest contractures were found at the MCP joint: 44° on average. The contractures at the PIP and DIP joints were 34° and 16°, respectively.

One week after PNF the mean TPED per ray was 30°, a 58% reduction from the preoperative TPED. This was a statistically significant reduction of the contracture (p = 0 .001). The results at the separate joints differed, however. The best results were found at the MCP joint with a 67% reduction of PED; 17° of PED remained. The reduction of PED at the PIP joint was 34% (24° remained) and at the DIP joint was 56% (8° remained).

Five weeks later the results were better than 1 week after treatment: the overall reduction of TPED measured 63%. The results at the MCP joint still were best, with a TPED reduction of 75%, followed by a 61% reduction at the DIP joint and a 33% reduction at the PIP joint (Table 3).

Table 3: The reduction of passive extension deficit (PED) one week and six weeks post-treatment in percentages of the original contracture

	One week		Six weeks		
	PNF 88 rays	LF 78 rays	PNF 88 rays	LF 76 rays	P value[b]
MCP	67 +/- 31	83 +/- 28	75 +/- 26	87 +/- 22	0.003
PIP	34 +/- 40	53 +/- 44	33 +/- 42	49 +/- 46	0.062
DIP	55 +/- 58	100 +/- 0	61 +/- 59	83 +/- 40	0.441
TPED	58 +/- 35	73 +/- 39	62 +/- 32	79 +/- 25	0.001

[a] Student t-test at six weeks

Limited fasciectomy.

Before surgery mean TPED in the LF group was 62°, and again the largest contractures were found at the MCP joint (mean, 42°). The contractures at the PIP and DIP joints measured 34° and 28°, respectively.

After 1 week the mean TPED was 15°, a reduction of 73% (p = 0 .001). Here the largest reduction in TPED was found at the DIP joint: 6 joints were treated and none had any extension deficit left. At the MCP joint an average reduction of 83% was obtained (a TPED of 9° remained) and at the PIP joint the average reduction was 53% (a TPED of 14° remained).

Six weeks after treatment the TPED had improved further, with an average reduction of 79%. This was caused mainly by a further reduction of the contracture at the MCP joint, which averaged 5°—a TPED reduction of 87%. The results at the DIP and PIP

joints worsened a little: the DIP reduction measured 83% and the PIP reduction measured 49% (Table 3).

Percutaneous needle fasciotomy versus limited fasciectomy.

The preoperative TPED of the 2 groups did not differ significantly: 66° (SD, 36°) per ray in the PNF group versus 62° (SD, 36°) per ray in the LF group (p = 0.549). The Tubiana score also was equal in the 2 groups (p = 0 .226).

Limited fasciectomy resulted in a statistically significant greater reduction of the flexion contractures compared with PNF (after 1 week, p = 0.002; after 6 weeks, p = 0.001).

The results at the MCP joint differed statistically after both 1 and 6 weeks (Table 3). The results at the PIP joint differed significantly after 1 week and in favor of LF but after 6 weeks this significance has disappeared. Results at the DIP joint did not differ significantly.

When we analyzed the data using the Tubiana classification it appeared that PNF and LF have a comparable outcome if the finger is graded as Tubiana I. The higher the Tubiana stage, however, the more limited the effect of PNF, especially if the finger was staged as Tubiana III or Tubiana IV (Tables 1 and 4).

Table 4: Reduction of TPED as percentage of preoperative value following PNF versus LF by Tubiana grade at six weeks

	PNF	LF	P value[a]
	n= 88 rays	n= 76 rays	
Tubiana I (PNF=28, LF = 29)	71 +/- 45	82 +/-33	0,329
Tubiana II (PNF=38, LF =32)	67 +/- 26	78 +/- 22	0,071
Tubiana III (PNF=16, LF = 11)	46 +/- 15	75 +/- 17	0,000
Tubiana IV (PNF=6 , LF = 4)	47 +/- 8	79 +/- 27	0,004

[a] Student t-test

Secondary Outcome Parameters

Complications.

Table 5 shows the relevant complication rates of the 2 groups. In the PNF group 33 minor complications were recorded; these consisted of 29 skin fissures and 4 cases of paresthesia. No major complications occurred.

Table 5: Complications at one week

	PNF	LF	P value [a]
	60 hands	57 hands	
Infection requiring antibiotics	0	1	0.487[b]
Haematoma needing treatment	0	1	0.487[b]
Skin slough	0	0	
Skin fissure	29	n.a.	
Sympathetic Dystrophy	0	0	
Paresthesia	4	13	0.013
Changed Semmes-Weinstein	0	1	
Digital nerve injury requiring repair	0	1	0.487[b]
Re-operation in operating theatre	0	0	
Flexor tendon division	0	0	

In the LF group we noted 13 minor complications (all cases of paresthesia) and 3 major complications: infection, hematoma, and digital nerve injury. The digital nerve injury was inflicted in a hand in which the transverse palmar fibers had been divided unintentionally. During excision of the pathologic cord the nerve was lifted out of its bed and this was not noted. The overall cumulative complication rate therefore was 50% in the PNF group and 30% in the LF group. If we look at the major complications the cumulative complication rate in the PNF group was 0% and in the LF group it was 5%.

Besides those complications at 1 week after treatment there were 7 patients in the PNF group and 45 patients in the LF group with a flexion deficit of 0.5 cm or more. In none of these cases, however, was this caused by a flexor tendon division. After 6 weeks there were no patients in the PNF group with flexion deficits and in the LF group there were 19 patients with flexion deficits (mean, 0.6 cm). Two patients still had flexion deficits of more than 1.5 cm. Those patients did not have flexion deficits before surgery.
If a patient's hand function did not improve as fast as expected he/she received physiotherapy. This was true for 6 patients in the PNF group and 8 patients in the LF group.

Patient satisfaction.

Patients treated with PNF were more satisfied with the function of the hand at 6 weeks than those treated by LF ($p = 0.003$). Limited fasciectomy gave patients significantly more discomfort ($p = 0.002$). When asked if they would choose the same treatment again in the future both groups answered that they would do so.

Disabilities of the arm, shoulder, and hand questionnaire.

A total of 114 patients filled out DASH questionnaires; however, only 50 patients from the PNF group and 47 patients from the LF group filled out the questionnaires to such an extent that they could be processed and analyzed statistically.

Before surgery DASH scores did not differ statistically between groups: 16 (SD, 14) in the PNF group and 14 (SD, 12) in the LF group ($p = 0.584$). One week after treatment the mean DASH score in the PNF group had increased to a level of 19—which was not significantly higher than the preoperative level—and decreased to 12 after 2 weeks. This reduction continued, with a mean score of 9 after 5 weeks of treatment.
In the LF group the DASH score measured 49 after 1 week and did not return to the preoperative level until after 5 weeks (score, 16).
The DASH scores of both groups differed significantly at all time points after treatment, with a p value of .000 at 1,2,3, and 4 weeks and a p value of .017 at 5 weeks.

DISCUSSION

This study is the first part of a long-term study that will follow up patients with Dupuytren's disease for 5 years after treatment with either PNF or LF. This article addresses specifically the outcome of PNF and LF in the first 6 weeks after treatment. This first part is important because it specifically investigates the postulated benefits of PNF such as minimal invasiveness, quick functional recovery, equal outcome, patient satisfaction, and limited number of complications in a randomized controlled fashion. The second part is a long-term study and will focus on recurrence rate.

For this purpose patients were randomized into 2 groups with an equal distribution of Tubiana degree, TPED, and demographics by means of pulling a random envelope out of a box. The demographics and contractures were similar to those described in previous studies (Foucher 1992). We performed LF on 57 hands and PNF on 60 hands. Patients were treated only once in the PNF group or the LF group. We calculated a cumulative complication rate as previously performed by McFarlane and McGrouther (McFarlane1990).

Some technical points about PNF have to be made to prevent damage to nerves. Only a very limited amount of local anesthesia (0.1–0.2 mL) should be administered at the selected puncture site. The pathologic cord itself is insensible but the nerve is not if it is not numbed. If the nerve is approached too closely the patient will report a strong electric current sensation at the tip of the treated digit. The patient should be asked to report this immediately and the needle should be redirected in such an instance.

One might wonder if a spiral cord presents greater risk during treatment. This is not the case because the course of the displaced nerve is quite standard: it lies relatively superficial at the junction of the palm and the base of the finger. This location should be avoided during treatment. In addition, because the spiral bands course deep to the neurovascular bundles after leaving the central band and because the neurovascular bundles are embedded in subcutaneous fat at that location, the presence of fat between the skin and the pathologic cord near the web should raise a high level of suspicion for a nerve displaced by a spiral cord, and it would not be logical to perform PNF at that location; the cord lies relatively deep. These are the main reasons why spiral nerves are not damaged often if the procedure is performed correctly.

The hands of the LF group were bandaged for 1 week whereas the hands treated by PNF were unwrapped after 24 hours. This may have caused some bias in the results of hand function after 1 week. In addition hand therapy was not standard in all cases and was initiated only if the return of hand function was delayed. This regimen may have caused a higher rate of reduced flexion in both groups.

We used DASH questionnaires to score disabilities of the upper extremity. The Dutch translation of the DASH questionnaire has been proven to be a reliable and valid instrument for assessing upper-extremity disabilities (Veehof 2002). The preoperative DASH scores were equal to previously reported normative data from the United States (Hunsaker 2002).

The results of this study concerning short-term outcome suggest that overall LF is superior to PNF, especially when the Tubiana degree is III or IV. Results at the DIP joint were not statistically different because numbers were small (10 in the PNF group vs 6 in the LF group). At the PIP joint the difference between LF and PNF was almost statistically different. Complication rates of LF were higher than those of PNF.

Patients were satisfied equally with LF and PNF but patients treated by PNF reported a better direct function of the hand and less discomfort after treatment.
This was substantiated by the DASH scores, which were significantly lower in the PNF group, indicating that patients were less disabled after PNF than after LF in the first 5 weeks after treatment. This was exactly what we had expected beforehand.

Percutaneous Needle Fasciotomy

Badois et al, the French rheumatologists who reintroduced PNF, performed PNF in 138 patients and found that 81% had good or excellent primary results, with a Tubiana score of 1 or less (Badois 1993). In the group of patients with stage IV disease 48% had good results. Duthie and Chesney performed percutaneous fasciotomy on 82 patients (Duthie 1997). They reported an overall improvement rate of 69%. In 1997 Bleton et al performed a prospective study on 59 patients (Bleton 1997). Sixty-one percent of the patients had good results, with an improvement of more than 50%. Foucher et al reported an immediate improvement of 72% in 1998 and 76% in 2001 (Foucher 1998, 2003).

Our results are not as good as those described in previous studies. With a mean improvement of 38° or 63%, there is a discrepancy. At first thought this might have been caused by our inexperience. Before we started this study, however, we performed a pilot study in which 51 patients with a mean contracture of 61° were treated by PNF. Together we treated 74 rays and the mean overall improvement was 76%. This outcome is comparable with the outcomes of the studies described earlier. The discrepancy suggests that PNF is not suitable for just any patient, but that when selected carefully part of the population of patients with Dupuytren's disease could benefit very well from this minimally invasive treatment.

Another reason for the disappointing results could be that Badois et al performed PNF at a mean of 2 to 3 sessions (Badois 1993). We performed only 1 session on each patient.

A third reason for the difference in outcome is probably the selection criteria; Foucher did not treat young patients or patients with skin involvement and used PNF at an earlier stage than they would have performed surgery (Foucher 2003).

The primary results of PNF in our study were quite reasonable concerning Tubiana stages I and II, but in stages III and IV we had improvement rates of only 46% and 47%. The results of our hands show that PNF is not suitable for the more serious contractures, as also had been concluded previously by Foucher (Foucher 2003).

Limited Fasciectomy

In the literature the results after LF vary from 53% in severe contractures (Weinzweig 1996) to 65% (Denkler 2005) and 76% (Hoet et al 1988). In this study the mean reduction of TPED was 79%.

A comparison of our results from PNF and LF show that only in stages I and II are the results of these treatments equal.

Complications

Regarding complication rates in the literature our results from PNF are comparable with those reported by Foucher (Foucher 2003) Badois (Badois 1993(and Bleton (Bleton 1997). Four patients reported paresthesia, but when we used the Semmes-Weinstein needles the sensibility had not diminished, suggesting that this was caused by neuropraxia. This neuropraxia was probably the result of nerve stretching during the procedure.

McFarlane and McGrouther in 1990 reported a cumulative complication rate of 19% for LF. In our series we report a complication rate of 30%. This is caused mainly by a high rate of paresthesia. Of the 13 patients responsible for this rate only 1 had an objectively diminished sensibility using Semmes-Weinstein monofilaments. We expect that all other cases of paresthesia will resolve in time.

As for reduced flexion the flexion deficit was small: in 17 of 19 patients the distance between the pulp and the distal palm crease was 1 cm or less. Many patients were not using the hand after 6 weeks as much as they had before surgery; this could be attributable to stiffness and discomfort at the level of the scar. We do not expect that this loss of flexion is permanent in all these patients and we will follow up the patients and report on this.

Patient Satisfaction and DASH Scores

Patient satisfaction in the PNF and LF groups was almost equal. Although the outcome of PNF is significantly worse than that of LF patients apparently appreciate the fact that there is an immediate improvement of hand function and that they experience little discomfort.

The DASH scores exemplify this remarkable difference in disability of the upper extremity. After 5 weeks the differences between LF and PNF still are significant. We expect, however, that the scores in the LF group will continue to decrease over time and end at the same level as those of the PNF group. We will report on this in the future.

Overall PNF is less effective than LF as a treatment for Dupuytren's disease, especially in cases with moderate to severe contractures. The difference is especially true at the MCP level. At the PIP joint the difference is borderline significant and at the DIP joint no difference in short-term outcome was found. The complication rate of PNF is low, however, and patients do not have to be admitted to the hospital. Finally, patients recover more quickly from PNF than from LF. Therefore PNF is useful to treat patients with Tubiana grade I and II disease to whom quick recovery is important. Careful selection of patients helps to get maximum results from treatment with PNF.

A long-term extension of this randomized clinical trial that will address a number of unanswered questions about PNF versus LF, especially regarding the chance of recurrence, is currently underway in our centre.

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CHAPTER FIVE:

THREE-YEAR RESULTS OF FIRST-EVER RANDOMIZED CLINICAL TRIAL ON TREATMENT FOR DUPUYTREN'S DISEASE: PERCUTANEOUS NEEDLE FASCIOTOMY VERSUS LIMITED FASCIECTOMY

Van Rijssen A.L., ter Linden, H, Werker, P.M.N. In: Charles Eaton, M. Heinrich Seegenschmiedt, Ardeshir Bayat, Giulio Gabbiani, Paul Werker, Wolfgang Wach, editors. Dupuytren's Disease and Related Hyperproliferative Disorders- Principles, Research, and Clinical Perspectives. Springer, 2012; 281-288

SUMMARY

In this chapter we describe the 3-year follow-up results of our randomised controlled trial on percutaneous needle fasciotomy (PNF) and limited fasciectomy (LF) for Dupuytren's disease.

This study shows that after three years recurrence after PNF (64%) is more frequent than after LF (9%). We also found that younger patients get recurrent disease sooner after treatment for Dupuytren's disease whichever treatment they received.

Satisfaction with the results of treatment was high in both groups, but in the LF group higher than in the PNF group. Nevertheless, patients who had previously undergone PNF were keen to have their recurrences treated by PNF again.

PNF is an appropriate treatment for elder patients who require fast recovery of hand function and are willing to accept the drawback of an increased recurrence rate.

INTRODUCTION

Percutaneous needle fasciotomy (PNF) is a treatment for Dupuytren's disease that exists in its current form since the late 1970's. This treatment was invented by French Rheumatologists, but is essentially a modification of the first treatment for Dupuytren's disease ever: aponeurotomy or fasciotomy, performed by Sir Henry Cline in 1777, the year Baron Guillaume Dupuytren was born (Cline, 1777). Recently this treatment regained popularity because of the growing demand for fast recovery, low complication rate and minimal invasiveness (Lermusiaux and Debeyre, 1980). Disadvantages of this technique are its lower effectiveness for moderately severe and severe forms of the disease (Tubiana stages 3 and 4) and its reported high recurrence rate (Citron and Nunez 2005, Ullah 2009, Jurisic 2008, Foucher 2001 Van Rijssen and Werker 2006b).

Limited fasciectomy (LF) still is the most frequently performed treatment by hand surgeons around the globe. It is hampered by a relatively longer recovery period and reasonably high complications rates, especially in recurrent cases (McFarlane and McGrouther 1990, Rodrigo 1976, Tubiana 1999, Coert et al 2006). In our first report of our on-going randomized clinical trial on the comparison of LF and PNF, we showed that results in the lower Tubiana stages I and II were similar, but that LF was slightly more effective than PNF for higher Tubiana stages in Dupuytren's disease. Importantly, functional recovery following treatment was significantly faster following PNF (Van Rijssen et al 2006a). In a pilot study we had found that recurrence rates following PNF after a mean of 33 months were similar to those reported by others (Van Rijssen and Werker 2006b).

To this date, no long-term results of randomized trials on PNF and LF have been published. The aim of this study was to fill this gap. We studied the effect on Total Passive Extension Deficit (TPED), patient satisfaction and recurrence rates up to 3 yrs follow-up in two groups of patients that had been randomly assigned to both treatment arms.

METHODS

Study design

This study was designed according to and approved by the Medisch Ethische Toetsings Commissie, the local Medical Ethics Committee, in January 2002.

From August 2002 to January 2005 we considered every patient with primary Dupuytren's disease who presented at our department for this study. Written consent was obtained from all patients.

Inclusion criteria were a Total Passive Extension Deficit (TPED) of at least 30° in the MCP joint, PIP joint or DIP joint, the existence of a clearly defined cord and willingness to participate in this trial.

Exlusion criteria were patients who received previous surgery for Dupuytren's disease on the hand they presented with, patients who were not allowed to stop their anticoagulants, patients generally unfit for surgery, and patients with a specific treatment modality wish.

Study candidates were examined by either PMNW or HTL. During examination, TPED of MCPJ + PIPJ + DIPJ was measured, as well as flexion deficit using a goniometer and sensibility using the Semmes-Weinstein monofilaments. Patients were asked to fill out a questionnaire about their health status, functional recovery, satisfaction with the treatment and demographics.

Randomisation

Randomization was carried out by a secretary, by means of pulling a sealed envelop from a box, which contained a note, stating either PNF or LF. This determined which treatment the patient was to receive. For elaborate patient demographics we refer to our previous study (Van Rijssen et al 2006a).

Surgical Technique

Treatment was performed by HTL or PMNW in random order. Patients were treated within one month after inclusion in this study.

PNF was performed as an outpatient procedure in the same way as previously described by Lermusiaux and Tyssedou (Lermusiaux 1980). Under local anesthesia for the skin only, the cords were divided using a 25-gauge needle at as many places along the cord as necessary to achieve maximal passive extension. A small dressing was applied for 24 hours. Patients were encouraged to start practicing the hand immediately after the procedure. They did not receive formal hand therapy. All hands were treated only once.

LF was performed under general or regional anesthesia using a palmar Skoog incision in combination with Bruner-type incision in the digits, which allowed skin transposition if necessary. A compressive bandage was applied which the patient was instructed to wear for 7 days until the first visit to the outpatient clinic. Patients were encouraged to practice extension and flexion of the fingers immediately after the anesthesia had worn off. Hand therapy was not standard but available if indicated.

Follow-up

Following the 6 weeks interval, patients were seen in the outpatient clinic at 6 months, and then yearly after treatment. During this visit we recorded the amount of passive extension deficit of each joint and calculated the TPED, sensibility, flexion deficit and signs of recurrence or extension of the disease. Patients were asked to fill out a questionnaire concerning their satisfaction with the treatment. Every follow-up for this study was performed by one of the authors.

Definition of recurrence

Recurrence was defined as an increase of extension deficit of at least 30 degrees compared to the 6 weeks values as the result of disease activity in the area previously treated. Extension was defined as an increase of extension deficit of at least 30 degrees compared to the 6 weeks values due to disease activity outside the area previously treated.

Statistics

Statistical analysis was performed using statistical software (SPSS software, SPSS Inc. Chicago, IL). We used the chi square test for categorical data. The student's t-test was used for recurrence and patient satisfaction. Linear-by-linear association tests were used to define age versus recurrence differences. Patients were stratified into the following groups for this purpose: 0-35 years, 36-45, 46-55, 56-65, 66-75, >75. We used Kaplan-Meier curves for survival. Significance was set at a p-value of less than 0.05.

RESULTS

At six weeks post treatment 111 patients were still in the study and had complete data sets. In these patients in total 115 hands were treated, since four patients were treated bilaterally. Ninety-four of these patients were men. Distribution of sexes was equal in both treatment arms, p = 0,529. The mean age of patients at follow up was 63 years in both groups, p = 0,972. Fifty-four limited fasciectomies had been performed and 61 percutaneous needle fasciotomies.

Recurrence after LF

Three years after surgery 8 patients with 8 treated hands were lost to follow-up due to severe disease or death. Forty-two hands showed no signs of recurrence (91,3%), and 4 had recurrence (8,7%).

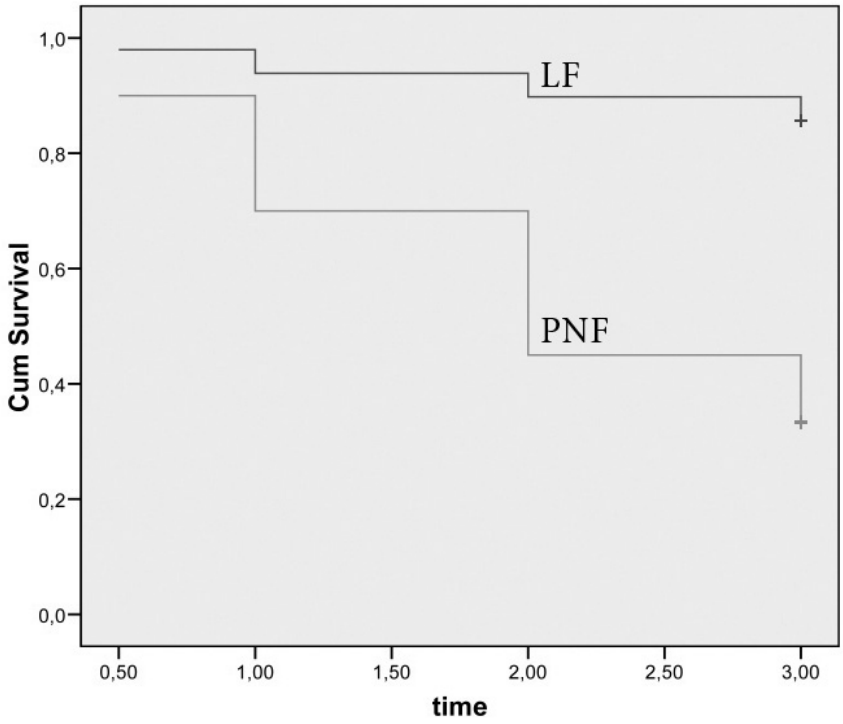
Recurrence after PNF

In the PNF group, 5 patients with 6 treated hands were lost to follow-up, 35 hands showed signs of recurrence (63.6%) and 20 hands showed no signs of recurrence (36.4%).

LF versus PNF

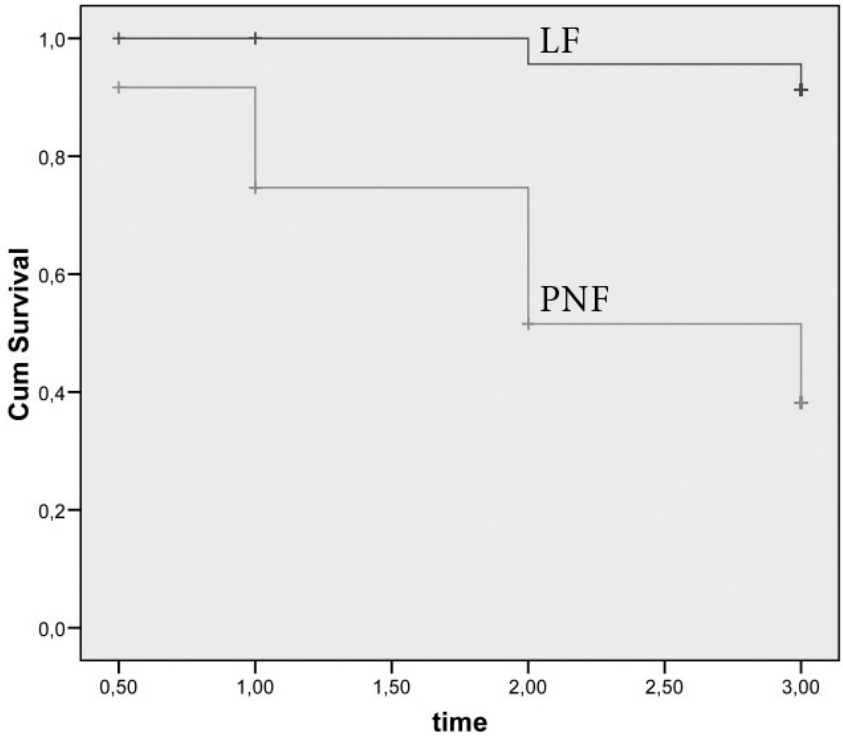
The recurrence rate in the LF group is significantly smaller, p =0,000.
Because we did not know if the patients that had been lost to follow-up, had recurrent disease or not we calculated worst-case and best-case scenarios. These are illustrated in Figures 1 and 2. They show that even if all lost to follow-up patients would have had recurring disease, the difference between LF and PNF was still striking.

Graph 1: Worst-case scenario. Kaplan-Meier survival curves with both treatment modalities



On the x-axis time is shown in years post-treatment. On the y-axis cumulative survival is shown, in which 1,0 means 100% of patients were still included in the study (not lost to follow-up or having recurrent disease). In this case all "lost to follow-up" patients were allocated as having recurrent disease.

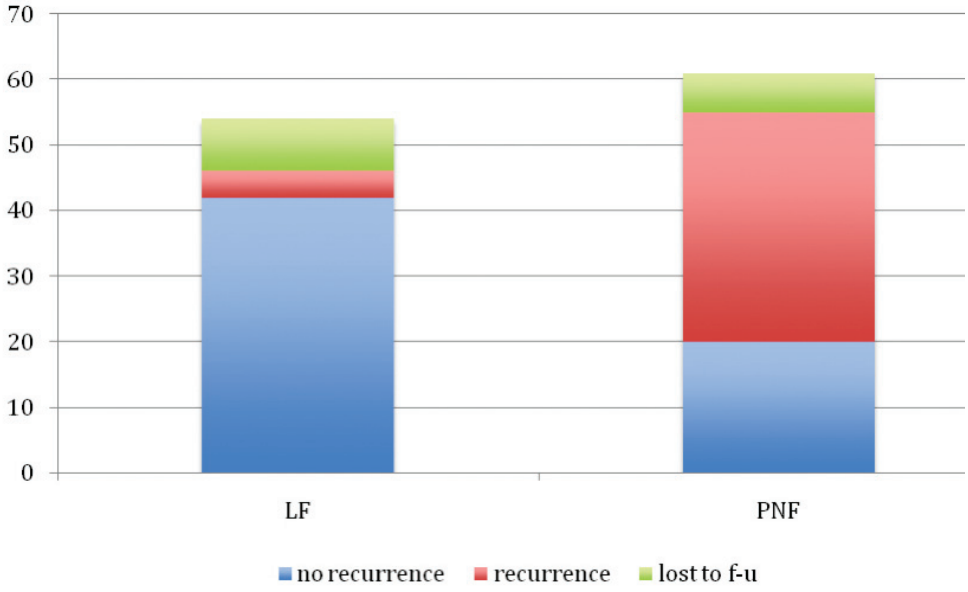
Graph 2: Best-case scenario. Kaplan-Meier survival curves with both treatment modalities



On the x-axis time is shown in years post-treatment. On the y-axis cumulative survival is shown, in which 1,0 means 100% of patients were still included in the study (not lost to follow-up or having recurrent disease). In this case all "lost to follow-up" patients were allocated as having NO recurrence.

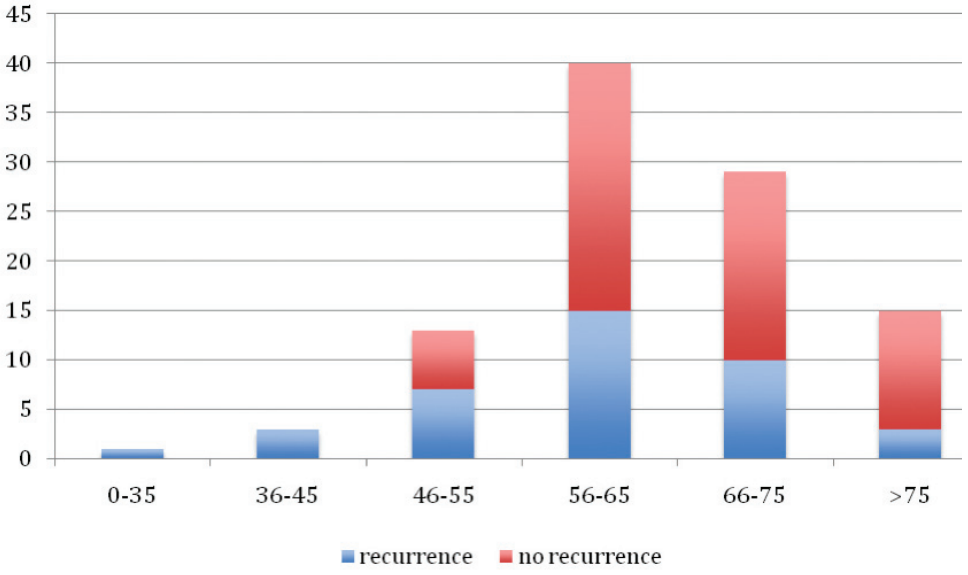
Figure 3 illustrates differences in recurrences and percentages of patients lost to follow-up.

Figure 3: Recurrence rates in the LF group and in the PNF group at 3 years



On the x-axis the 2 different treatment modalities are shown, on the y-axis the number of hands treated.

Figure 4: Numbers of patients who are disease-free and have recurrent disease at different age groups



On the x-axis different age-groups are shown in years at time of treatment. On the y-axis numbers of patients are shown (LF and PNF combined).

Treatment for recurrent disease

In the LF group, one patient chose to have his recurrence treated by PNF. Three chose not to be treated for their recurrence. Therefore, none of the patients in the LF group who had recurrent disease chose to undergo LF again.

In the PNF group, of 35 patients with recurrent disease, 21 (60%) chose to undergo a second PNF treatment. Six patients (17%) wanted to be treated by LF and the remaining 8 (23%) chose not to undergo treatment for their recurrent disease. In these patients, the increase in extension deficit did not impair their hand function.

Sensibility recovery

During LF, one patient suffered from iatrogenic digital nerve injury. This was recognized immediately and the nerve was repaired microsurgically in the same session. His preoperative Semmes-Weinstein test was 2.83 on the affected side of the finger. Postoperatively this dropped to 4.93 to turn back to the preoperative level of 2.83 after 6 months.

Satisfaction

Patients were asked the following questions:
Q1: Are you satisfied with the results of your treatment? (0 = not at all, 10 = excellent)
Q2: Would you choose this treatment modality again? (0 = no, 10 = yes, definitely)

The results show that although patients are significantly less satisfied with the results of their treatment after PNF, they are still considering undergoing the same treatment modality again. These figures display satisfaction either at time of recurrence (when the study is terminated for the specific patient), or at the time of the 3-year interval (at the end point taken in this study).

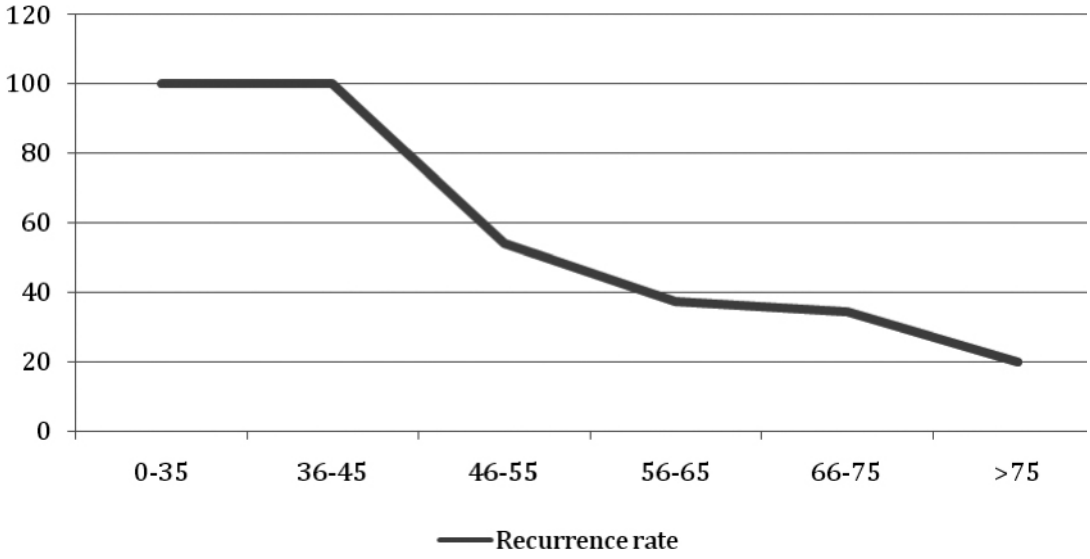
Table 1:

	PNF	LF	P value
Q 1: results	6.0	8.2	0,007
Q 2: treatment modality	7.3	8.0	0.165

Recurrence versus age at time of treatment

Due to small numbers of recurrence in the LF group, we were not able to draw conclusions on the age-effect on recurrence between groups. However, we were able to prove that the higher age at time of treatment, the lower the chance of getting recurrent disease for both groups together, p= 0,005. As shown in Figures 4 and 5 all patients older than 56 are less likely to get recurrent disease than to remain disease-free. It also shows that the highest age groups have the lowest recurrence rates.

Figure 5: Recurrence rates at different age groups



On the x-axis different age-groups are shown in years at time of treatment. On the y-axis the percentage of these patients that had a recurrence is shown (LF and PNF combined).

DISCUSSION

This study focuses on recurrence rates in the first three years after PNF or LF. We randomized our patients into two groups. Patient demographics and contractures were equally distributed as we have shown before and were comparable to groups in other studies (Van Rijssen et al. 2006a). Our direct postoperative results and results at 6 weeks post treatment were comparable to those reported in literature.

"Recurrence" after treatment for Dupuytren's disease however, is an ill-defined entity in current literature. The most commonly used definition is "reappearance of Dupuytren's tissue in a previously operated zone" (Tubiana 2000, Becker 2010).
Reported recurrence rates differ enormously: from 0-73 % for all different techniques combined. Comparison is difficult because of lack of standardized definitions of recurrence and follow-up duration.

We defined recurrence as a worsening of 30º or more compared to the postoperative result after 6 weeks. Our definition deviates somewhat from the definition mentioned above. This definition of recurrence could not be used in this study however. The reason for this is that after PNF the diseased tissue is still present in the palm. Nodules that are present before the procedure often remain unchanged or soften. The cords are divided but over time they seem to reconnect.

We feel that we used a reproducible and clinically important definition of recurrence. Reappearance of Dupuytren's tissue does not have to impair one's hand function. We chose a worsening of 30º because this corresponds to Hueston's tabletop test and is an indication for surgery in our treatment centre.

Recurrence after LF

In our study, the recurrence rate after 3 years was 9%.
Citron and Nunez reported their results on a randomized study in which they studied the differences between longitudinal incisions closed with Z-plasty or Bruner's incision closed with V-Y plasties (Citron and Nunez 2005). Only one ray was treated in every patient. Recurrence was defined as the reappearance of Dupuytren's tissue

in previously operated field. The demographics of their patients were comparable to those of ours. They found 33% recurrence for the former and 18% for the latter after a period of 2 years.

Jurisić retrospectively studied the population of Primorsko-Goranska County, Croatia, and found a 73% recurrence rate after partial fasciectomy after a mean follow-up of 7 years (Jurisić 2008). Recurrence was defined as the development of new Dupuytren's disease lesions including the smallest palpable nodule irrespective if it caused a contracture in the same area where fasciectomy had been performed. Thirty-four percent of those required further surgery.

Degreef reports in a previously unpublished study a recurrence rate of 43% after segmental fasciectomy with a minimum follow-up of 2 years (Degreef, this book, Chapter# Section#).

Ullah et al. performed a prospective study on limited fasciectomy in which they compared direct closure with the use of a "firewall" full thickness skin graft (Ullah 2009). They found no significant difference in recurrence, which was 13.6% average after a follow-up of 3 years for the group treated by fasciectomy alone. The definition of recurrence in this article is not clear, but the text says "progressive recurrence of contracture".

At this point in our study, our recurrence rates after LF are low. When we compare them to other studies, it seems our recurrence rate is lower than those reported in literature. This can partly be explained by the variations in definitions of recurrence. It is anticipated that recurrence rates will increase in time.

Recurrence after PNF

Compared to studies on LF, recurrences following PNF are even more ill-defined and hard to balance. In our study, the recurrence rate as defined by an increase in TPED compared to the 6 weeks results was 63% after 3 years follow-up. This figure is very similar to that of previously published series. In a pilot for this study we found 65% recurrence after a mean of 33 months (Van Rijssen et al 2006b). Foucher reviewed

100 rays after a mean of 3.2 years (Foucher 2001) and found a recurrence rate of 58%. These similar data indicates that we executed PNF well. Therefore we are confident that the longer term results, which we expect to publish within the near future will be reliable too. And this is even more so, since we are the first to publish a prospective randomized study on the results of PNF versus LF and therefore there has not been selection bias.

Age versus recurrence

As Hindocha et al pointed out that age of onset less than 50 years old will increase chances of recurrent disease (Hindocha 2006). To our knowledge, this is the first study that proves that there is an overall relationship between age at treatment and chance for recurrence. The higher the age of the patient at time of treatment, the lower the chances of getting recurrent disease.

Treatment of recurring disease

Recurrence does not necessarily mean that there is a need for reoperation. Twenty-eight percent of the patients who had a recurrence according to our definition chose not to undergo further treatment at that moment. This is probably because the extension deficit was less severe than the preoperative disease and did not impair hand function as it initially did.

Satisfaction

Satisfaction was high for both PNF and LF. Patients receiving LF were at 3 years significantly more satisfied with the results of their treatment than those who underwent PNF. However, many patients who suffered recurrent disease chose to undergo PNF again. This indicates that many patients prefer a minor procedure with fast recovery at the expense of the increased chance of an early recurrence.

CONCLUSIONS

* Recurrences after PNF are far more frequent and occur sooner than after LF
* Recurrence after PNF at three years is 63% and after LF 9%.
* Satisfaction is high for both treatment modalities, but patients treated by LF are significantly more satisfied with their results than those patients treated by PNF
* Many patients choose to undergo PNF as their secondary treatment in spite of the disadvantages named above
* No matter which treatment modality, recurrences occur more frequently in the younger patients than in the older patients.

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CHAPTER SIX:

FIVE-YEAR RESULTS OF A RANDOMIZED CLINICAL TRIAL ON TREATMENT IN DUPUYTREN'S DISEASE: PERCUTANEOUS NEEDLE FASCIOTOMY VERSUS LIMITED FASCIECTOMY

6

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ABSTRACT

Background: The increasing armamentarium to treat Dupuytren's disease indicates a need for comparative studies. Here the 5-year follow-up results of a randomized controlled study that compared percutaneous needle fasciotomy (PNF) and limited fasciectomy (LF) is presented.

Methods: 111 patients with 115 affected hands with a minimal passive extension deficit of 30° were randomly assigned to the treatment arms. Follow up was at one and six weeks, six months, 1,2,3,4, and 5 years after the operation. Outcome parameters were Total Passive Extension Deficit (TPED), patient satisfaction, finger flexion and sensibility. Furthermore, disease extension during follow-up was recorded. The primary end point was recurrence in any treated ray, defined as an increase of TPED of >30°. Ninety-three patients reached the primary endpoint.

Results: Recurrence rate after 5 years in the PNF group (84.9%) was significantly higher than in the LF group (20.9%), $p < 0.001$, and occurred significantly sooner in the PNF group ($p = 0.001$). Higher age at time of treatment decreased the recurrence rate, $p=0.005$. No indications were found that other diathesis characteristics influenced recurrence. Patient satisfaction was high in both groups, but in the LF group significantly higher than in the PNF group. Despite this, many patients (53%) preferred PNF treatment in case of disease recurrence.

Conclusions: PNF is the preferred treatment for elderly patients with Dupuytren's disease and for those willing to accept the drawback of a possible early recurrence in the context of the advantages of PNF, such as fast recovery, low complication rate and minimal invasiveness.

INTRODUCTION

Percutaneous needle fasciotomy (PNF) is a treatment for Dupuytren's disease that was reinvented by French rheumatologists in the late 1970s, and is essentially a modification of the treatment that was first suggested by Sir Henry Cline in 1777: aponeurotomy or fasciotomy (Lermusiaux 1980, Cline 1777). PNF is gaining popularity because of the growing demand for fast recovery, low complication rate, and minimal invasiveness (Lermusiaux 1980). In a previous report on our randomized clinical trial we have shown that functional recovery during the first six weeks was significantly faster following PNF than after limited fascietomy (LF) (Van Rijssen 2006a). We also found that PNF is not as effective for moderately severe and severe forms of the disease (Tubiana stages 3 and 4) as LF (Van Rijssen 2006). As major drawback, the reported recurrence rates after PNF have been relatively high (Foucher 2001, Van Rijssen 2006b, 2011). Worldwide, hand surgeons most frequently use LF, despite its relatively longer recovery period and reasonably high complication rates, especially in recurrent cases (Citron 2005, McFarlane 1990, Rodrigo 1976, Tubiana 1999, Coert 2006, Ullah 2009, Jurisić 2008)

To date, a randomized controlled trial comparing the two treatments with long term follow up had not been performed. The purpose of the present study is to fill this gap and to report on our five years recurrence rates. This study also allowed us to analyze whether pre-operative disease factors predispose for recurrence. Our primary outcome measure was Total Passive Extension Deficit (TPED) of each treated ray. Patient satisfaction with results of treatment, and treatment preference in case of recurrence was also studied.

METHODS

Study design

This study was designed according to and approved by the local Medical Ethics Committee in January 2002. From August 2002 to January 2005 every patient with

Dupuytren's disease who presented at our Department was assessed for enrolment in the study. Inclusion criteria were total passive extension deficit of at least 30° in any ray, excluding the thumb, the existence of a clearly defined palmar cord and willingness to participate in the trial. Written consent was obtained from all patients at study entry. Excluded were patients with postsurgical recurrence or extension of the disease after earlier treatment, patients who were not allowed to stop their anticoagulants, patients generally unfit for surgery, and patients with a specific treatment preference. Patients were asked to fill out a questionnaire about their health status and demographic characteristics and these data have been published before (Van Rijssen 2006). The Abe diathesis scoring system was applied at the end of the study to evaluate its influence on recurrence and extension in our study (Abe 2004).

The diathesis score (D) is calculated as: D = a + b + c + d + e + f, in which "a" is bilateral hand involvement (with = 1, without = 0), "b" is little finger surgery (with = 1, without = 0), "c" is early onset of disease (with = 1,without = 0), "d" is plantar fibrosis (with = 2, without = 0), "e" is presence of knuckle pads (with = 2, without = 0), and "f" is radial side involvement (with = 2, without = 0).

Randomization (3).

Randomization was done through the pulling of sealed envelopes by a secretary.

Surgical technique

PNF was performed as outpatient procedure using local anaesthesia for the skin only (Van Rijssen 2006). Cords were divided using a 25-gauge needle at as many places as necessary to achieve maximal passive extension. A small dressing was applied for 24 hours. Patients were encouraged to start practicing the hand immediately after the procedure. All hands were treated only once.

LF was performed under regional or general anaesthesia using a palmar Skoog incision in combination with Bruner-type incision in the digits. All diseased fascias were removed and the skin was closed following flap transposition as indicated. A light compressive bandage was applied which the patient was instructed to wear for 7 days

until the first visit to the outpatient clinic. Patients were encouraged to practice extension and flexion of the fingers immediately after the anaesthesia had worn off.

Follow-up

Following the six weeks interval (Van Rijssen 2006), patients were seen at 6 months, and at 1,2,3,4 and 5 years after treatment. Follow-up investigation consisted of goniometry to assess extension deficit, assessment of sensibility and satisfaction. For the latter, the following two questions were asked:

Q1: How satisfied are you with the results of your treatment? (1 = not at all, 10 = excellent)

Q2: How likely is it that you would choose this treatment modality again? (1 = no, 10 = yes, definitely)

At the start of the study, recurrence was defined as an increase of TPED of at least 30° compared to the 6 weeks follow-up values in the ray previously treated. Extension was defined as disease activity outside the area previously treated. Recently a number of studies have been published using a definition of recurrence by joint (Badalamente 2000, 2002, 2007, Hurst 2009). To enable comparison of our data with these studies, their definition, i.e., "a return of contracture (20°) in successfully treated joints", in which successfully treated joints had reached a TPED of 0-5°, was also applied.

STATISTICS

Statistical analysis was performed using statistical software version 15.0 (SPSS software, SPSS Inc. Chicago, IL). The chi square test was used for categorical data. The Student's t-test was used for recurrence and patient satisfaction. Linear regression analyses were performed to study age versus recurrence differences. Correlation regression analyses were applied to calculate the influence of demographics on recurrence rate. Significance was set at a p-value of less than 0.05.

RESULTS

In total 93 patients (84%) reached the primary end point or could be followed for 5 years. Their demographical details are summarized in Table 1. In these 93, 125 joints were treated with LF and 167 joints with PNF. There were no statistical differences in various characteristics between the PNF and LF groups. The mean PED's of the study population at the start of the study and the outcome figures at six weeks are summarized in Table 2.

Table 1: Demographics and patient characteristicsrole

		LF (n = 41)	PNF (n = 52)	P value
Gender	Male	32	44	0.42
	Female	9	8	
Knucklepads		6	9	0.77
Ledderhosen		7	3	0.07
Dupuytren's in family		20	18	0.15
Epilepsy		0	2	0.21
Diabetes		4	7	0.61
Early-onset disease before 50		14	19	0.88
Abe-score > 4		5	6	0.97
Mean age (years)		63.1	62.8	0.86

Table 2: Mean PED's by joint, of that part of the study population that reached the primary end point, or completed the 5 years follow up, at the start of the study and the outcome figures at six weeks by joint.

N=93 patients	PNF Treated joints: 167			LF Treated joints: 125		
	Pre treatment PED (mean)	Six wks results (mean)	% Successfully treated joints*	Pre treatment PED (mean)	Six wks results (mean)	% Successfully treated joints *
MCPJ	43°	9°	55%	41°	1°	94%
PIPJ	35°	21°	26%	32°	9°	47%

* reduction to 0-5° PED

Recurrence after LF and PNF

During five years follow-up 33 hands in 31 patients treated with LF did not develop recurrence (76.8%), while 9 hands did (20.9%). One hand showed extension (2.3%). After 5 years, only eight hands treated with PNF showed no signs of recurrence (15.1%). The other 45 hands (84.9%) had reached the primary end point of the study. The recurrence rate in the LF group was significantly smaller, $p < 0.001$ (95% confidence interval 1,597-2,628), and recurrence occurred significantly later after LF than after PNF ($p = 0.001$). Figure 1 shows the Kaplan-Meier survival estimates of the study groups. For both procedures, the distribution of recurrences appeared to be normally distributed. For LF there were 2 recurrences at two years, 2 at three years, 3 at four years and 3 at 5 years. For PNF: 6 recurrences at 6 months, 10 at 1 yr, 13 at two years, 7 at three years, 8 at four years and 1 at 5 years.

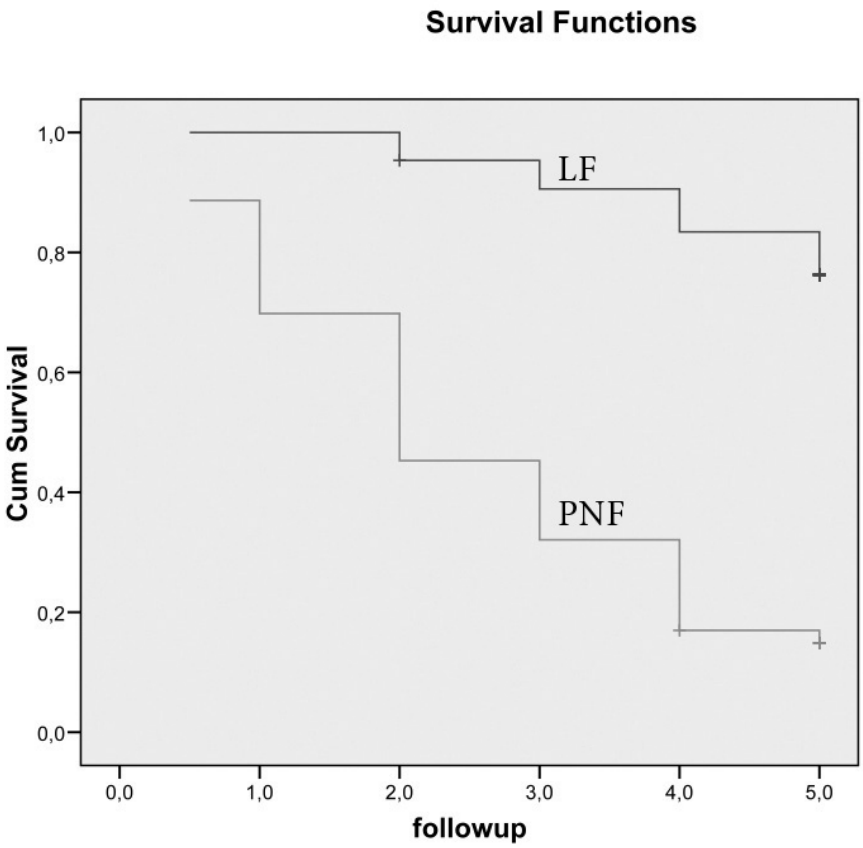


Figure 1: Kaplan-Meier survival estimates for both treatment modalities

Decrease of rate of patients in the study (y-axis) with time (x-axis, in years of follow up) as the result of reaching the primary end point of the study (increase of TPED of >30°).

Pictures 1 and 2 show a clinical example of a 61-year-old male who was treated by LF on the 4th digit of his left hand. After 5 years, there was no recurrence in this finger, but extension of the 5th digit was noted. Pictures 3 and 4 show preoperative and post-operative and results after one year of a 63 year old male patient who was treated by PNF. He later suffered from recurrent disease.

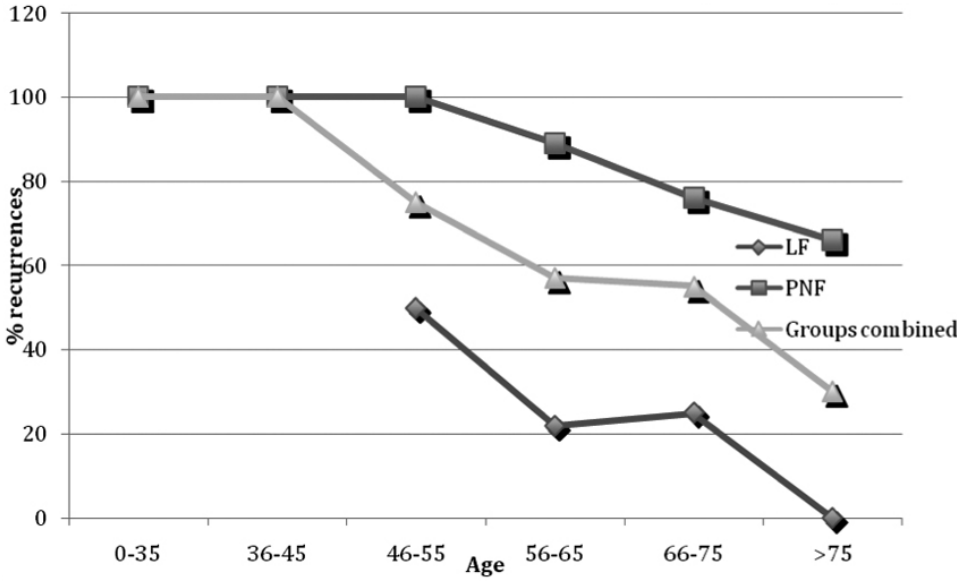
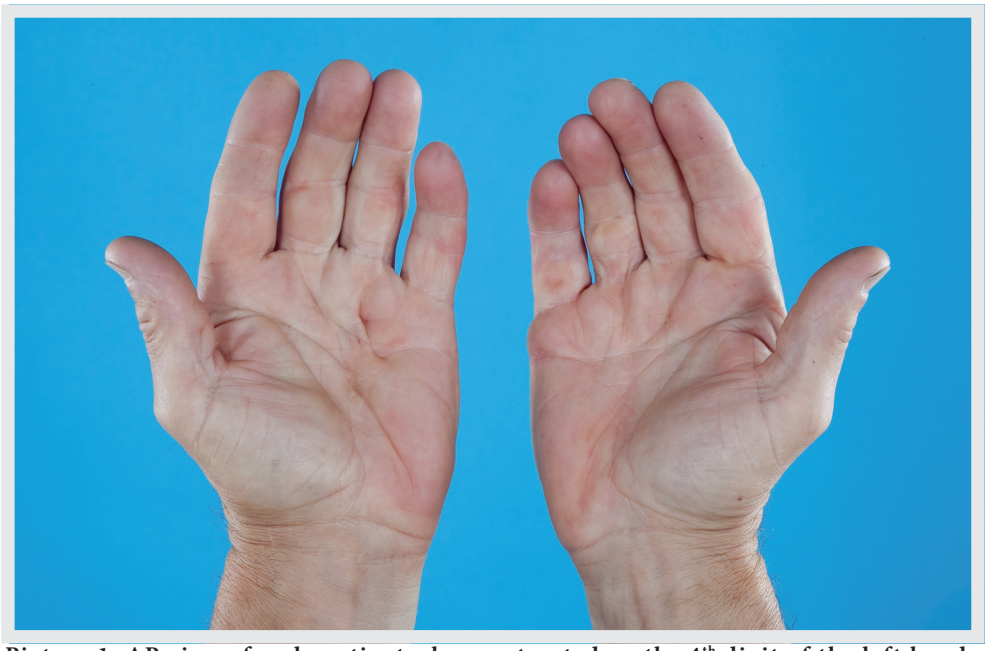


Figure 2: Recurrence rates in different age groups

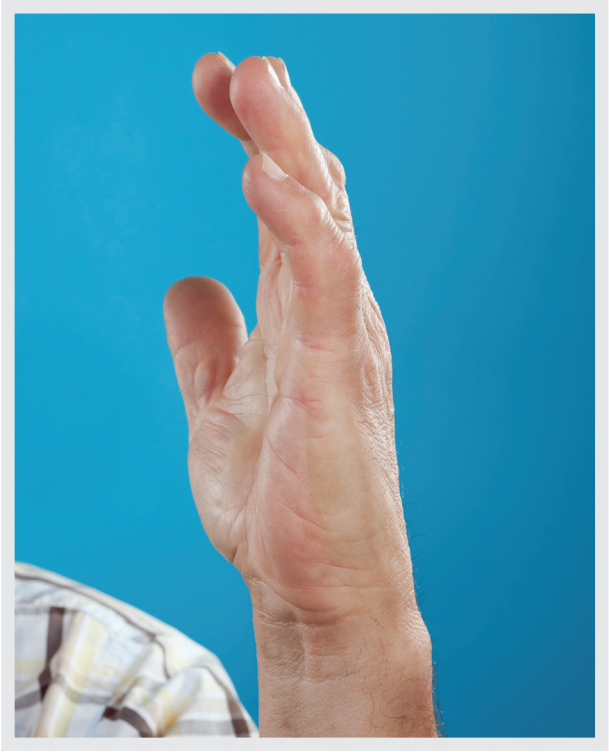
On the x-axis different age groups are shown in years at time of treatment. On the y-axis the percentage of these patients that developed recurrence is shown (LF, PNF, and combined).

Although not statistically significant in the LF group, due to the small number of recurrences, a higher age at the time of treatment seemed to predict a delay of recurrence (p=0.07). In the PNF group the age-recurrence correlation was statistically significant at p = 0.04. When the LF and PNF groups were taken together, the older age group showed less recurrent disease than the younger patients, p = 0.005 (Figure 2). No factors correlating with recurrent disease were found other than age at the time of treatment (Table 3).



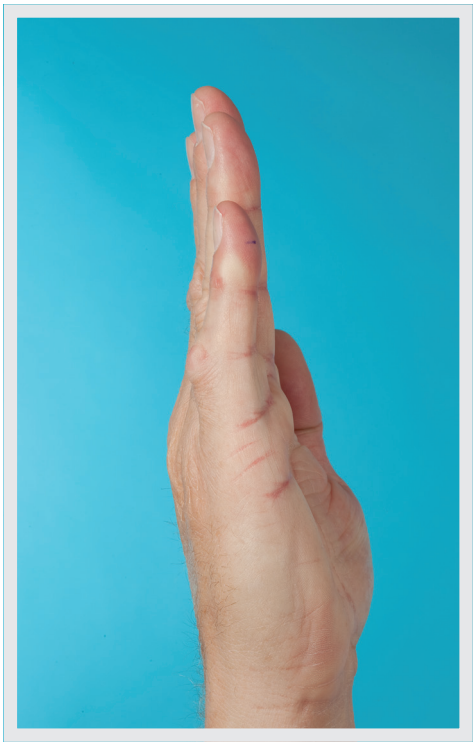
Picture 1: AP view of male patient who was treated on the 4th digit of the left hand

Age and recurrence



Picture 2: After 5 years he suffered from extension in the 5th digit

Picture 3: Preoperative view of a 63-year old patient before PNF on his left 5th digit



Picture 4: The same patient as in picture 3, postoperatively after PNF of the 5th digit on the left hand.

Influence of feature on recurrence	P value	Odd's ratio
Gender	0.29	1.84
Knucklepads	0.25	1.44
Ledderhosen	0.98	1.01
Diabetes	0.78	1.20
Epilepsy	0.99	1E+009
Fifth digit involvement	0.06	3.10
Radial side involvement	0.39	1.29
Early onset disease	0.06	2.41
Family members with Dupuytren's disease	0.58	1.27

Table 3: the influence of risk factors on recurrence

Abe's scoring system for predicting recurrence and extension

Abe's scores for both treatment groups were calculated. Four out of 10 patients with recurrence or extension in the LF group had an Abe's score higher than 4; in the PNF group 9 out of 45 had an Abe's score higher than 4. These scores did not influence the chances of recurrence; p=0.23 in the LF group and p=0.19 in the PNF group. Therefore, our study does not support Abe's hypothesis; a higher score did not correlate with recurrence in our study.

Choice of treatment for recurrent disease

In the LF group, four of nine patients chose to have their recurrences treated with PNF. Six patients (five with recurrences and one with extension) chose not to be treated. None of the patients in the LF group who presented with recurrent disease chose LF again.

Twenty-six patients out of 45 with recurrent disease in the PNF group, chose to undergo a second treatment with PNF. Seven patients preferred LF. The remaining 12 patients did not opt for treatment for recurrent disease.

Satisfaction

The average patient satisfaction score was significantly higher in the LF group (8.3), as compared to the PNF group (6.2, $p < 0.001$). The score for choosing the same procedure as preferred future treatment was 8.7 in the LF group, which was significantly higher than the score of 7.0 in the PNF group ($p = 0.008$). The scores for both questions were strongly correlated to recurrent disease. In patients with recurrence, satisfaction with treatment results was significantly less ($p < 0.001$) as compared to the patients without recurrence (Odd's ratio 0.61). These patients also expressed less preference for the same treatment ($p =0.02$, Odd's ratio 0.83).

DISCUSSION

This study focused on Dupuytren's disease recurrence rates that occurred during a 5 years follow up period after treatment by percutaneous needle fasciotomy (PNF) or limited fasciectomy (LF). A number of definitions can be found in the literature for "recurrence" after treatment for Dupuytren's disease. For example, McFarlane used the definition "recurrent joint contracture sufficient to require further operation" (McFarlane 1990). Hueston used "appearance of new Dupuytren's tissue within the area cleared at operation" and this definition is the most widely used one (20). Some authors, such as Makela et al. and Badois did not define "recurrence" (McFarlane 1990, Mäkelä 1991, Badois 1993).

Hueston's definition of recurrence could not be used, since in PNF no tissue is removed (Hueston 1984). Therefore, recurrence was defined indirectly, i.e., "an increase of the Total Passive Extension Deficit of 30° or more in a ray compared to the result at 6 weeks post treatment". This measure is reproducible and clinically more relevant than the other definitions. A worsening of digital extension of 30° was chosen because it corresponds to Hueston's tabletop test and is considered the minimal contracture to qualify for surgery at our centre.

Recurrence after LF

In a previous study on the 3-year results of the same cohort of patients we found a recurrence rate of 9% (Van Rijssen 2011). At 5 years, the recurrence rate has increased to 20.9%. This figure compares favourable to other studies, although comparison is hampered due to varying definitions, and a lack of 5-year follow up data from other studies. We found only two studies with long-term data that we consider to some extent relevant for comparison. Jurisić et al. retrospectively studied the population of Primorsko-Goranska County in Croatia and found a 73% recurrence rate after limited fasciectomy and a mean follow-up of 7 years (Jurisić 2008). However, they had defined recurrence as the development of new Dupuytren's disease lesions in the area where fasciectomy had been performed, including the smallest palpable nodule irrespective of a presenting contracture. Thirty-four percent of these recurrences required further surgery.

Foucher described his results on the open palm technique in 54 patients in 1992 with a 5.6-year follow-up period. Recurrence was not clearly defined. The recurrence rate in his study was 41%.

Recurrence after PNF

In our study, 85% of the patients developed recurrence during 5 years follow-up. This recurrence rate is the highest ever published for PNF. Nevertheless, we believe that the results of others would have been similar if they had followed their cohorts for 5 years and had used a comparable definition. In our analysis at 3 years, the recurrence rate was 63%. This figure is very similar to that of previously published series with the same follow up period. In our pilot we found 65% recurrence after a mean of 33 months (Van Rijssen 2006b), while Foucher reviewed 100 rays after a mean of 3.2 years and found a recurrence rate of 58% (Foucher 2001). The only study that reported 5 year results was from the group of Badois et al (Badois 1992). They reported a recurrence rate of only 50%, but their definition of recurrence is unclear.

Recurrence after LF and PNF compared to those after treatment with collagenase

In the last decade the results of various studies on the application of collagenase for Dupuytren's disease have been published (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010). The results of these studies have been presented in a different manner than ours. All collagenase studies looked at the effect of treatment at each joint individually. The treatment is defined "clinically successful" when correction of the deformity decreases to within 0-5˚ of full extension.

If we reanalyze our data accordingly, 94% of the treated MP-joints in the LF group, and 55% in the PNF group reached this endpoint. In the PIP joint the corresponding figures are 47% following LF and 26% following PNF. Our results were achieved with only one treatment, whereas patients treated with collagenase often needed multiple treatment sessions. In the study by Hurst et al, 76% of MCP joints reached the primary endpoints and 40% of PIP joints (Hurst 2009). A comparison with our data shows that we achieved better results with LF than Hurst et al obtained with collagenase. A single treatment with PNF, however, seems to be somewhat inferior to up to three injections with collagenase.

At present there are only two long-term follow-up studies available in which collagenase was used, one with 8 years follow-up, the other with 2 years (Watt 2010, Hurst 2009,). The former study (Watt 2010) also used another definition of recurrence, i.e., it was defined as any degree of loss of extension as compared to full extension. If we apply this definition in our study, the recurrence rate for the MCP joint would be 21% in the LF group and 57% in the PNF group (p = 0.00). For the PIP joint rates are 21% for the LF group and 70% in the PNF group (p = 0.00). In Watt's study, recurrence rate in the MCP joint was 68% and in the PIP joint 100% after 8 years. Recurrence rates of collagenase therapy at eight years are therefore comparable, if not worse compared to our PNF results after 5 years.

In a study conducted by Hurst and Badalamente in 2007 the recurrence rate defined as a return of contracture of at least 20° in successfully treated joints was 19% after 2 years. If we would apply this in our study, recurrence rates would be as follows. In the MCP joint, we reached "success" in 72.1% (132/183 joints). Recurrence rate would be 5.3% (4 out of 76 joints) in the LF group and 21.8% (12/55 joints) in the PNF group after 5 years. In the PIP joint, we reached success in 34.3%. In the LF group, recurrence was 5.3% (1 of 19 joints showed recurrence), and in the PNF group, recurrence would be 23.5% (4 out of 17 joints). These results indicate that the recurrence rate after collagenase is considerably higher than after LF and PNF, even after a considerably shorter follow-up period.

Age versus recurrence

As Hindocha et al pointed out in their study, an age of onset that is younger than 50 years increases chances for recurrent disease (Hindocha 2004). To our knowledge, our study is the first that showed a general correlation between age and disease recurrence.

Dupuytren's diathesis

Our findings do not corroborate with those of many authors supporting the view that Dupuytren's diasthesis is a risk factor for recurrence or extension. We were unable to find a statistically significant influence of fifth digit involvement, early-onset, radial disease, familial predisposition, ectopic lesions, gender or comorbidities, such as diabetes and epilepsy, on the appearance of recurrence.

McFarlane reported 5-year results on limited fasciectomy with the open-palm technique, and was also unable to prove the effect of Hueston's diathesis. This finding, as well as the establishment of an effect of age on recurrence, suggests that his findings are consistent with ours (McFarlane 1990).

Patient satisfaction

Patient satisfaction was high for both PNF and LF treatments. Patients who had received LF were at 5 years significantly more satisfied with their treatment than those with PNF. The outcomes were influenced in a negative way when recurrence took place. However, many patients who suffered recurrent disease chose to undergo PNF again. This indicates that many patients are likely to prefer a minor procedure with fast recovery at the expense of a higher chance of an early recurrence.

Conclusions

Although PNF is equally effective for mild to moderate Dupuytren's disease (Tubiana I and II), as we have shown in previous studies, recurrence rates are significantly higher than after LF. A higher age at disease presentation correlates with less tendency to recurrence. For this reason, we believe that PNF treatment is best suitable for well-informed elderly patients with relatively mild contractures (Tubiana I and II) and for those who are willing to accept a higher recurrence risk in the context of a lower complication rate, fast recovery and minimal invasiveness.

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CHAPTER SEVEN:

PERCUTANEOUS NEEDLE FASCIOTOMY FOR RECURRENT DUPYTREN'S DISEASE

Van Rijssen AL, Werker PMN. J Hand Surg Am. Accepted under revision March 2012

ABSTRACT

Purpose: The increasing armamentarium to treat Dupuytren's Disease includes percutaneous needle fasciotomy (PNF), a minimally invasive technique, which has proven to be effective for the treatment of primary disease. We were unable to find reports on its effectiveness and long-term outcome in recurrent Dupuytren's disease. This study aims to fill this gap.

Methods: 30 patients with recurrent disease in 40 rays were studied, with a mean follow-up period of 4.4 years. Primary outcome measures were Total Passive Extension Deficit (TPED) reduction, and interval to a second recurrence, defined as an increase of more than 30° compared to the result at the end of previous treatment. Complications were noted.

Results: TPED reduction was 76%. PNF was especially effective for the MCP joint, with an average reduction of 93%, whereas average reduction in the PIP joint was 57%. Fifty percent of cases did not develop a secondary recurrence during follow-up. The other fifty percent of patients did, and recurrence was treated within 1.4 years on average after PNF. By means of PNF, tertiary treatment was postponed on average 2.9 years starting from the initial treatment for Dupuytren's disease. All secondary recurrences were successfully treated by limited fasciectomy, according to the patients' wish. No major adverse effects were noted.

Conclusions: PNF can effectively be applied for recurrent disease and 50% of cases remain free of recurrence for a mean of 4.4 yrs. If a secondary recurrence occurs, it does so relatively early after treatment: patients must therefore be willing to accept this uncertainty in the context of the advantages of PNF, such as fast recovery, low complication rate and minimal invasiveness.

INTRODUCTION

Dupuytren's Disease is an incurable chronic condition leading to finger contractures in most of the cases. Following surgical treatment fibromatosis generally recurs or extends and causes recontracture (Millesi 1981). Several risk factors have been suggested to influence the interval to, and severity of recurrence (Hueston 1984, Hindocha 2006, Abe 2004, Van Rijssen 2012a). These are onset of the disease before the age of 40, familial predisposition, presence of ectopic lesions, bilateral disease, radial involvement and fifth digit involvement.

Reported recurrence rates vary from 0-73% for limited fasciectomy (LF) (Van Rijssen 2012, Foucher 2001, Jurisic 2008), to 20-100% for collagenase injections (Hurst 2009, Watt 2010), 50-85% for percutaneous needle faciotomy (PNF) (Van Rijssen 2012a, Badois 1993,Van Rijssen 2006a, Van Rijssen 2012b) and 8.4-47 % for dermofasciectomy (Armstrong 200, Kelly 1992). The reason why these figures vary so largely is the lack of standard definitions for recurrence, and varying follow-up periods. One of the few available randomized controlled studies showed PNF and LF to be similarly effective for contracture release in lower Tubiana stages, and recovery following PNF much faster than after LF, but also that the recurrence rate 5 years after PNF is four times higher as compared to LF (Van Rijssen 2012a, Van Rijssen 2006 b). Despite these differences, many patients still prefer PNF over LF because it is minimally invasive and has a short recovery period. Also for recurrent disease, many patients choose PNF treatment.

Studies with a reasonable follow up period that look into the efficacy and durability of treatment for recurrent disease are lacking. It has been reported that surgery for recurrences is more difficult and hampered by more complications than treating the first disease episode (Coert 2006). The aim of the present study was to investigate the effectiveness of PNF for the treatment of recurrent Dupuytren's disease, to search for influences of known risk factors on the development of recurrences, and to investigate the amount of time gained by performing PNF before further treatment becomes advisable.

METHODS

We retrospectively reviewed all the patients included in our previous RCT on PNF versus LF, who developed recurrence during the 5-year follow-up period (Van Rijssen 2012a). IRB approval was not obtained, as this is not required in our centre for this type of research.

In 45 hands treated by PNF an increase of the Total Passive Extension Deficit (TPED) of at least 30° in one or more rays was found: this was our definition of recurrent disease. Twenty-six patients (26 hands) in the PNF group requested PNF for treatment of their recurrent disease, while 7 requested LF. The remaining 12 patients refused treatment for their recurrences. In the group initially treated with LF, 4 out of 10 patients, (4 hands) wanted treatment for their recurrent disease by PNF.

In this study we specifically focused on these 30 patients who underwent PNF for their recurrent contracture following prior successful treatment with PNF (n=26 patients, 26 hands) and LF (n=4 patients, 4 hands). Patients were treated in an outpatient setting under local anaesthesia. The cord responsible for the flexion contracture of the ray was sectioned at as many levels as possible in the palm and finger, depending on the location and extent of the disease, using a 25 Gauge needle mounted on an 10ml syringe. After division of the cord, the affected finger was passively extended to pull the ends of the sectioned cord apart and to obtain maximal release of the contracture. A small dressing was applied for 24 hours. For a more detailed description of PNF, we refer to our previous study (Van Rijssen 2006b), and to the article on PNF by Eaton (Eaton 2011).

Patients did not receive any specific post-operative hand therapy regimen or splint therapy.

We looked at the effects of PNF for recurrent disease, investigated whether secondary treatment sufficed or tertiary treatment was necessary, and if so, after how long. We also compared the patient groups requiring second and third treatment with respect to differences in known risk factors for developing recurrences. Patient demographics are outlined in Table 1.

Table 1: Patient characteristics

		Number of patients (and percentage)
Gender	Male	22 (73%)
	Female	8 (17%)
Mean age (yrs) at time of 2nd PNF		59
Ectopic Disease		9 (30%)
Positive family history for DD		12 (40%)
Associated Diseases (Epilepsy, Diabetes)		6 (20%)
Early-onset disease before 50		13 (43%)
Abe's diasthesis (>4)		6 (20%)

Statistical analysis was performed using SPSS version 15.0 (SPSS software, SPSS Inc. Chicago, IL). The chi square test was used for categorical data. The student's t-test was used for the calculation of recurrence rate. Significance was set at $p < 0.05$.

RESULTS

Preoperative TPED was 50° (SD 21). Forty rays were treated: 4 middle fingers, 15 ring fingers and 21 small digits. These involved 23 rays in Tubiana stage I, 16 in Tubiana stage II, and one ray was classified as stage III according to the Tubiana system (Tubiana 1999). See table 2.

Table 2: The Tubiana Classification of Dupuytren's Contracture of the Fingers

Tubiana I	= TPED of 0-45°
Tubiana II	= TPED of 46-90°
Tubiana III	= TPED of 91-135°
Tubiana IV	= TPED of > 135°

Thirty MCP joint contractures were treated and 22 PIP joint contractures. See table 3.

Table 3: Contractures by joint

	MCP	PIP	MCP + PIP
No.	21	13	9

There was no significant preoperative difference in TPED in the initially LF or PNF treated groups, p= 0.406. The postoperative measurements of six patients were unavailable; only data on the necessity of their further treatment were present in these cases. In the other 24 cases, the mean remaining TPED after treatment was 13.1° (SD 17.4). These 24 patients were treated in 32 rays, of which 14 MCP joints were treated, 10 PIP joints, and 8 in both joints.

Contracture reduction following PNF was 76%, (SD 34.4). Again, there was no difference in TPED reduction, regardless whether patients were previously treated with PNF or LF (p = 0.331). Average passive extension deficit (PED) reduction in the MCP joint was 93%, whereas in the PIP joint it was 57%. The difference between PIP and MCP joints was statistically significant (p =0.000).

No serious adverse effects such as nerve injuries or flexor tendon injuries occurred. Skin fissures did occur, but none of them needed intervention.

The average follow-up of our patients was 4.4 years after PNF (SD 1.5; minimum 2, maximum 7 years). Of the 30 patients who underwent secondary PNF, 15 developed a contracture again and requested tertiary treatment (50% recurrence rate). Of the 24 patients from whom we had a complete data set, 11 developed a recontracture (46%). All were treated by LF. This modality was the choice of the patient after having been informed about the longer disease free interval of LF (15). LF was performed between 0.3-4 years, with an average of 1.4 year after the second PNF procedure (SD 1.9). Since the average time to the first recurrence had been 1.5 years, the secondary PNF treatment postponed LF 2.9 years on average.

We found no statistical differences in the distribution of known risk factors between the patient group requiring secondary treatment, and the patients who also received tertiary treatment. Age, ectopic disease and associated conditions, fifth digit involvement and age at onset of disease, did not seem to influence the development of recurrences (Abe 2004). Moreover, in this study, we could not demonstrate that the severity of PIP joint disease influenced the recurrence rate: p= 0.204. We were unable to find any differences in the outcomes between patients who previously received PNF or LF, most likely because the LF group was too small to allow statistical comparison.

DISCUSSION

This study aimed to investigate the short and long term effectiveness of PNF for recurrent DD and is the first of its kind. PNF as a treatment modality for recurrent disease resulted in an initial 76% reduction of TPED. PNF was especially effective for the MCP joint, with an average reduction of 93%. Fifty percent of the patients did not need any further treatment during the course of this study. However, after a mean follow-up of 4.4 years, the other 50% did require additional treatment. No known risk factors were found to influence the development of a second recurrence. The third treatment for all secondary recurrences was LF, which was performed on average 1.4 years after the second treatment.

Our reduction of TPED as a result of the second PNF was larger than we reported in our previous study on primary disease (Van Rijssen 2006a, Van Rijssen 2006b). We suggest this is partly caused by

1) The fact that preoperative measurements showed that contractures were slightly less severe than in the previous study, but most importantly:

2) We observed increased experience in our application and execution of the surgical technique, and dared to go more distal into the finger, which enabled us to gain better results.

The same arguments may apply to the lower recurrence rate. In one of our previous studies, we found 84.9 % recurrences after 5 years follow-up, compared to the current rate of 50% now after 4.4 years (Van Rijssen 2012a). Also, our direct results in both MCP joints as well as PIP joints were better than those previously reported by us.

We were unable to prove any influences of known risk factors on the occurrence of secondary recurrence, which is most likely explained by the fact that the sample size is relatively small.
We were unable to find any reports on PNF for recurrent disease, and therefore we cannot put our results in perspective of other researchers.
In a previous study, we proved that advanced age had an inhibitory effect on the appearance of recurrent disease (Van Rijssen 2006a). In the present study, this could not be reconfirmed. This is probably again caused by the fact that our study group was much smaller this time.

Our findings do not corroborate with those of many authors supporting the view that Dupuytren's diasthesis is a risk factor for recurrence or extension. We were unable to find a statistically significant influence of fifth digit involvement, early-onset, radial disease, familial predisposition, ectopic lesions, gender or co morbidities, such as diabetes and epilepsy, on the appearance of recurrences. In our study on the long-term effects of PNF and LF, we could not prove the influence of these risk factors either (Van Rijssen 2012a). McFarlane reported 5-year results on LF with the open-palm technique, and was also unable to prove the effect of Hueston's diathesis (McFarlane 1990). These findings are consistent with ours.

From the present study, we conclude that for both post-PNF and post-LF recurrences PNF leads to good immediate results. Secondary recurrences cannot be prevented and occur in 50% of cases after 4.4 years on average. These patients received a more invasive treatment modality, which was LF in all patients. Using PNF for treatment of the first recurrence, this procedure was postponed for 2.9 yrs. We found LF as a tertiary procedure not more complicated than in case of primary disease. However, the cords seem to be a bit broader and more diffuse than in primary disease.

These findings suggest that PNF is a valuable treatment method for patients with recurrent Dupuytren's disease.

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7

CHAPTER EIGHT:

CORRECTION OF CONTRACTURE AND RECURRENCE RATES OF DUPUYTREN'S CONTRACTURE FOLLOWING SURGICAL TREATMENT: THE IMPORTANCE OF CLEAR DEFINITIONS

8

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Submitted to The Journal of Hand Surgery, American Volume, December 2011

ABSTRACT

Objective: Several different surgical procedures have been used to treat Dupuytren's contracture, but only few studies have compared recurrence following contracture correction achieved with different interventions.

Methods: This study assessed definitions and rates of contracture correction and recurrence in patients undergoing surgical treatment of Dupuytren's contracture. A literature search was carried out in January 2011 using the terms "dupuytren's" AND ("fasciectomy" OR "fasciotomy" OR "dermofasciectomy" OR "aponeurotomy" OR "aponeurectomy") and limited to studies in English.

Results: The search returned 218 papers, of which 21 had definitions, quantitative results for contracture correction and recurrence, and a sample size of at least 20 patients. Definitions for correction of contracture and recurrence varied greatly among papers and were almost always qualitative. Percentage of patients who achieved correction of contracture (i.e., responder rate) when evaluated at various times after completion of surgery ranged from 15% to 96.2%. Recurrence rates ranged from 4.9% to 73%. Review of these studies underscored the difficulty involved in comparing correction of contracture and recurrence rates for different surgical interventions because of differences in definition and duration of follow-up.

Conclusions: Clearly defined objective definitions for correction of contracture and for recurrence is needed for more meaningful comparisons of results achieved with different surgical interventions.

INTRODUCTION

Dupuytren's contracture is a fibroproliferative disorder characterized by development of nodules and collagen cords within the palmar fascia of the hand that may shorten and cause progressive digital flexion deformity (Bobinski 2008, Townley 2006). The overall prevalence of Dupuytren's contracture is uncertain but is believed to range from 0.2% to 56% (Bayat 2007a, Hindocha 2009).

Diagnosis of Dupuytren's contracture is based on a focused medical history and physical examination, with family history, risk factors (e.g. smoking and alcohol consumption), and associated diseases (e.g., diabetes mellitus, liver disease, epilepsy) often taken into consideration. The most common presenting feature early in the course of the disease is the appearance of a solid painless nodule in the palm. In addition, about 5% of patients complain of local tenderness (Bayat 2007a). Dupuytren's contracture manifests bilaterally in many patients (but not necessarily in the same stage), and there is no firm relation to handedness. The most commonly affected digits are the ring and little finger, followed by the thumb, middle finger, and index finger. Dupuytren's contracture may also be associated with ectopic lesions, including Garrod's knuckle pads, Peyronie's disease, and Ledderhose's disease (Bayat 2007a, Trojian 2007, Dohlen 1996).

Currently, there is no "cure" for Dupuytren's contracture, and it is generally believed that the condition does not resolve spontaneously (Bayat 2006b). Nonsurgical treatments for Dupuytren's contracture include splinting, physiotherapy, radiotherapy, oral vitamin E, and intralesional steroid injections (Bayat 2006b, Rayan 2008). Injectable collagenase clostridium histolyticum (CCH) has also been used to treat Dupuytren's contracture and has been shown to be significantly superior to placebo in clinical trials (Hurst 2009, Gilpin 2010).

While nonsurgical interventions can be employed in patients with Dupuytren's contracture, surgery is still the most common intervention. Procedures include dermofasciectomy, standard limited fasciectomy, segmental fasciectomy, radical fasciectomy, open fasciotomy, and percutaneous needle fasciotomy (needle aponeurotomy) (Trojian 2007, Bayat 2006b, Rayan 2008, Frank 2001, McGrouther 2005, Moermans 1991).

Treatment outcomes for patients who undergo surgery for treatment of Dupuytren's contracture can be considered in 4 broad categories: initial response, risks for short- and long-term complications, and risk for recurrence (Benson 1998, Anwar 2007). Recurrence is relatively common in patients treated for Dupuytren's contracture, and rational selection of therapy depends on understanding the risk for this outcome with different interventions (Watson 1991). This systematic review provides information about the success of different surgical approaches to the treatment of Dupuytren's contracture, focusing on recurrence and considering the various criteria used to define successful treatment and recurrence.

METHODS

Collection of Publications

On January 17, 2011, a PubMed literature search was carried out using the terms "dupuytren's" AND ("fasciectomy" OR "fasciotomy" OR "dermofasciectomy" OR "aponeurotomy" OR "aponeurectomy") and limited to studies in English. No other limitations were placed on this search except that case studies reporting results for fewer than 20 patients were excluded. This search returned 218 papers (Appendix 1).

A total of 90 papers were eliminated since review of abstracts indicated that they did not contain any primary data regarding the use of a specific intervention and outcomes (initial correction of contracture or recurrence). The 128 papers remaining after this step are listed in Appendix 2. Full text of the remaining 128 papers was obtained and reviewed. During this review, studies were eliminated if there were results from fewer than 20 patients or if studies did not provide a description of the surgical procedure used, definitions for both correction of contracture and recurrence, and quantitative results for both of these outcomes. This resulted in a total of 21 studies that were included in the analysis. The following measures were tabulated for each of the remaining studies (note that not every study had information for each of the variables): number of patients, demographics (sex, age), clinical characteristics, type

of treatment, definition of correction of contracture and time when assessed, percentage of patients with correction of contracture, definition of recurrence and duration of follow-up, and percentage of patients with recurrence. For evaluation, studies were grouped into 2 categories with respect to surgical intervention: fasciectomy (including aponeurectomy) and fasciotomy.

RESULTS

Results from this analysis, including the number and characteristics of the patients treated, study design and surgical procedure, definitions for correction of contracture and recurrence, correction rate (i.e., percentage of patients meeting the criteria for initial treatment success), duration of follow-up, and recurrence rate are summarized in Tables 1 and 2 for the two major classes of surgical procedures carried out. Eighteen of the studies used some variation of fasciectomy (Table 1), and 3 studies used fasciotomy (Table 2). Sixteen of the papers were descriptions of case series, 2 were randomized clinical trials, 1 was a prospective single-treatment study, 1 was a non-randomized clinical trial, and 1 was a survey.

Correction of contracture was defined both quantitatively and qualitatively in the studies reviewed (Tables 1 and 2), but all analyses presented results as percentages of patients who met the stated criteria for correction (i.e., responder frequency). These ranged from 15% to 96.2%. However, it is very difficult to compare results from different trials because of the wide range of definitions for correction of contracture that were employed as well as differences in the times at which the initial outcome of the surgical procedure was assessed. Timing of evaluation was particularly varied and extended from 2–3 weeks to 2.5 years after the procedure (Anwar 2007, DeMaglio 1996). Detailed quantitative criteria for correction of contracture and timing of assessments were provided in only a few studies (Ullah 2009, Citron 2003b).

There was also great variability in how the studies defined recurrence and a correspondingly wide range of recurrence rates. Definitions of recurrence were qualitative in 20 of the 21 studies reviewed (95.2%). All of the qualitative definitions of recur-

rence can be paraphrased as "occurrence of the evidence of disease in the area of the operation." The single quantitative definition of recurrence was total passive extension deficit increase of ≥30° during follow-up compared with the immediate postoperative measurements (Van Rijssen 2006a). Another source of variability in assessment of recurrence is the wide range of follow-up durations in the studies reviewed (12 months to 10 years) (Anwar 2007, Kartik 1963). Recurrence rates ranged from 4.9% to 73% (Kartik 1963, Van Rijssen 2006b).

DISCUSSION

The results from this systematic review of the current literature underscore the difficulties in comparing the initial effectiveness and risk for recurrence of different surgical interventions in patients with Dupuytren's contracture. Definitions of both correction of contracture and recurrence are variable, and the time at which these outcomes are evaluated differ greatly from one study to another. This is largely due to the fact that the studies reviewed were not aimed at providing information about the comparative efficacy of different surgical procedures for Dupuytren's contracture. Rather, they were retrospective evaluations of outcomes for a given procedure carried out by one surgeon or at a single center. Such studies have a very different goal from randomized controlled clinical trials and generally do not include information about patient inclusion/exclusion criteria, an a priori definition of endpoints, or timing of evaluations. Interpretation of case reviews of a series of patients being managed with a single procedure is also limited by the possibility that results may be biased by inclusion of patients likely to have good outcomes from that intervention based on the investigator's past experience (Hess 2004). Moreover, all of the surgical interventions assessed in this review appear to be more effective than no treatment, and placebo-controlled studies of these established procedures would provide little useful information. Controlled comparative studies would be difficult because of the need to standardize the surgical interventions being evaluated across multiple physicians, centers, and patients.

Ideally, surgical interventions for Dupuytren's contracture should be assessed in large-scale, randomized, double-blind, controlled clinical trials with well-defined patient populations and time points for evaluation. Double blinding is almost impossible in studies that compare surgical interventions for the correction of Dupuytren's contracture. It has been accomplished in randomized, double-blind placebo-controlled studies of injection of CCH for the treatment of Dupuytren's contracture (Hurst 2009, Gilpin 2010). Additionally, these studies also carefully and quantitatively defined the entry criteria for the trial. Patients had fixed-flexion contractures of the metacarpophalangeal (MCP) or proximal interphalangeal joint (PIP) ≥20° in one finger (excluding the thumb). They had MCP joint contractures of 20° to 100° or PIP joint contractures of 20° to 80° and were unable to simultaneously place the affected finger and palm flat on a table (Hurst 2009, Gilpin 2010).

Comparison of surgical treatments for Dupuytren's contracture could also be facilitated by consistent and quantitative definitions of both correction of contracture and recurrence. The definitions for both correction of contracture and recurrence were qualitative in all but a few of the studies included in this review (Tables 1 and 2). The most detailed definition for correction of contracture in the studies reviewed was: good correction if ≤15° loss of extension remained after treatment for either the MCP or the PIP joint and flexion to the palm was complete; fair if there was 15° to 25° loss of extension and the patient could flex to within 1 cm of the distal palmar crease; and poor if the patient had greater loss of flexion or extension (Gelberman 1980). More often, correction of contracture was defined qualitatively as clearance of disease, freedom from disease, or full correction of contracture (Hueston 1963, Rombouts 1989, Dias 2006). A detailed quantitative definition of correction of contracture was employed in the phase 3 studies of CCH for the treatment of Dupuytren's contracture. In these studies, correction of contracture was defined as a reduction in primary joint contracture to 0° to 5° of full extension 30 days after the last injection. Presentation of results from these trials also included mean changes in range of motion for injected joints at 30 days after the last injection (Hurst 2009, Gilpin 2010). Definitions of recurrence in most of the studies reviewed were also qualitative. Examples include appearance of new Dupuytren's tissue within the area cleared at operation, reappearance of Dupuytren's disease in the cleared operative field, and the appearance of new fascial bands, determined by appearance and palpation, in an area where fasciectomy had

been previously performed (Hueston 2009, Nieminen 1986, Gelberman 1980). Comparison of the long-term efficacy of different treatments for Dupuytren's contracture would be facilitated by a quantitative definition of recurrence of the type employed in the phase 3 studies of CCH injection. In these trials, recurrence of contracture was defined as an increase in joint contracture to ≥20° in the presence of a palpable cord at any time during the study in primary joints that reached the criterion for correction of contracture (Hurst 2009, Gilpin 2010). An earlier study of CCH injection for the treatment of Dupuyten's contracture also employed the ≥20° definition of recurrence (Badalamente 2007).

Van Rijssen and colleagues have also used a quantitative definition (total passive extension deficit [TPED] increase of ≥30° compared with immediate postoperative measurements) to assess recurrence following percutaneous needle fasciotomy (Van Rijssen 2006a). A soon to be published five-year follow up of a randomized clinical trial comparing percutaneous needle fasciotomy and limited fasciectomy will also provide further insight into response to surgery and recurrence by using specific definitions for assessment of these parameters (Van Rijssen 2011b).

An important question that remains to be answered is what is the best approach to study interventions aimed at correcting Dupuytren's contracture? Assessments of CCH injection for the treatment of this condition and the upcoming comparative van Rijssen data may provide some guidance for changes (Hurst 2009, Gilpin 2010, Badalamente 2007, Van Rijssen 2011b). Becker and Davis have also suggested that objective measures for correction of contracture, well-defined follow-up intervals, and a consensus definition of recurrence be employed in studies of treatments for Dupuytren's contracture (Becker 2010).

In conclusion, results from the present analysis indicate high variability in the definition of both correction of contracture and recurrence and a corresponding wide range of outcomes reported in studies of surgical interventions for Dupuytren's contracture. Randomized controlled clinical trials provide the best approach to comparison of treatments but are difficult to carry out for this condition. At a minimum, development of consensus endpoints and approaches to follow-up of patients undergoing specific treatments may facilitate evidence-based recommendations for treatment of

Dupuytren's contracture. The detailed definitions for correction of contracture and recurrence and clear definition of timing for patient evaluations in clinical studies of CCH for the treatment of Dupuytren's contracture provide a good example of how this can be accomplished (Hurst 2009, Gilpin 2010).

ACKNOWLEDGEMENT

The authors wish to thank Bob Rhoads, PhD, consultant for MedVal Scientific Information Services, LLC, for providing medical writing and editorial assistance. This manuscript was prepared according to the International Society for Medical Publication Professionals' Good Publication Practice for Communicating Company-Sponsored Medical Research: the GPP2 Guidelines. Funding for this study and to support the preparation of this manuscript was provided by Auxilium Pharmaceuticals.

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Table 1: Fasciectomy (including Surgical Aponeurectomy)

Citation	Number of Patients	Patient Characteristics	Study Design and Procedure	Correction of Contracture Definition	Correction Rate	Recurrence Definition	Recurrence Rate
Hueston 1963[17]	224	Not stated	Case series–fasciectomy (limited in 202 patients; total in 22 patients)	Clearance of disease	47.3% over up to 5 years of follow-up	Appearance of new Dupuytren's tissue within the area cleared at operation	27.7% over up to 5 years of follow-up
Gelberman, 1980[18]	24	All patients were men; 45-67 years of age; average duration of disease of 8.5 years; deformity was mild in 8 patients, moderate in 7 patients, and severe in 9 patients; 6 had bilateral disease; fasciitis was present in the plantar fascia in 2 patients and Peyronie's disease was present in 2 patients	Case series–fasciectomy	Correction was good if ≤15° loss of extension remained after treatment for either the MCP or the PIP joint and flexion to the palm was complete, fair if there was 15°-25° loss of extension and the patient could flex to within 1 cm of the distal palmar crease, and poor if the patient had greater loss of flexion or extension	Results were good in 11 patients, fair in 12 patients, and poor in 1 patient over 18 months of follow-up	The appearance of new fascial bands, determined by appearance and palpation, in an area where fasciectomy had been previously performed	12.5% over 18 months of follow-up
Nieminen, 1986[19]	70	63 men and 7 women; mean age, 63 years	Case series–regional fasciectomy	No recurrence or extension of disease	No extension of disease was noted and 57% of hands had no recurrence over 47 months of follow-up	Reappearance of Dupuytren's disease in the cleared operative field	43% of hands over a mean of 47 months of follow-up
Rombouts, 1989[20]	63	54 men and 9 women; mean age, 59 years; 1 had early disease (presence of nodules in the absence of retraction), 66 had active disease (increasing retraction), and 10 had advanced disease (long-standing condition that has not worsened during recent months)	Case series–selective fasciectomy	Freedom from disease	29% over a mean of 63 months of follow-up	Appearance of new lesions (bands or nodules) determined by appearance and palpation in an already operated area	39% of hands over a mean of 63 months of follow-up
Foucher, 1992[21]	107	100 men and 7 women; median age at operation was 57 years and median duration of disease was 4 years; Garrod's knuckle pads were present in 11%, Ledderhose's disease in 5%, and Peyronie's disease in 2.5%; bilateral involvement was present in 42%	Case series–open palm with Bruner incisions	Improvement in mobility at 5 years	36%	Disease reappearing in a site that had been operated on	41% over a mean of 5.6 years of follow-up

Adam, 1992 [22]	85	74 men and 11 women; average age at time of operation was 57 years	Case series–partial fasciectomy	Outcomes were defined as excellent (full flexion and extension of the fingers, full function, and no recurrence), good (slight limitation of flexion or extension; recurrence, if present, was too slight to interfere with normal activity), fair (limitation of flexion or extension with joint stiffness, recurrence or extension causing some limitation of hand's function), or poor (no improvement in the initial range of movement or function, recurrence or extension causing serious loss of function)	Outcomes were rated as excellent or good in 56.6% of hands and fair or poor in 43.4% of 113 hands over a mean of 41 months of follow-up	Appearance of Dupuytren's disease in area cleared by operation	34% over a mean of 41 months of follow-up
Cools, 1994 [23]	28	25 men and 3 women; mean age at time of operation was 64 years; disease duration ranged from 1-32 years; 15% had severe disease according to Tubiana's classification; 25% had ectopic disease (18% knuckle pads, 7% plantar nodules)	Case series–partial fasciectomy with open palm technique	Freedom from recurrence and extension	15% of patients had no recurrence or extension over a mean of 2.5 years of follow-up	New Dupuytren's disease in the area operated on	33.5% over a mean of 2.5 years of follow-up
Foucher, 1995[24]	54	50 men and 4 women; mean age was 54 years; mean duration of disease was 3 years; 8 patients were in stage 4 of Tubiana and Michon's classification, 11 in stage 3, 25 in stage 2, and 10 in stage 1; 3 patients had associated ulnar nerve lesions at the elbow; 6 had knuckle pads, 3 had plantar fibromatosis, and 2 had Peyronie's disease.	Case series–open palm with transverse and Bruner incisions	Extension and flexion deficits at the MCP and PIP joints were measured before and after operation with a goniometer	Immediate post-operative median gains in extension were 49.2° for the MCP joint, 31.4° for the PIP joint, and 80.6° globally	Disease reappearing in a site which had been operated on	38.9% over a mean of 6.6 years of follow-up

MCP = metacarpophalangeal; PIP = proximal interphalangeal.

Table 1: Fasciectomy (including Surgical Aponeurectomy)

Citation	Number of Patients	Patient Characteristics	Study Design and Procedure	Correction of Contracture Definition	Correction Rate	Recurrence Definition	Recurrence Rate
Abe, 2004[25]	57	53 men, 4 women; mean age 61 years; mean disease duration 4.5 years; 23 ectopic lesions (12 knuckle pads, 11 plantar fibrosis, 1 Peyronie's disease)	Case series–subtotal fasciectomy	Percentage improvement of extension in each finger joint; an excellent result was defined as a 90%-100% improvement, a good result as a 70%- 89% improvement, a fair result as a 30%- 69% improvement, and a poor result as <30% improvement of the extension loss	Approximately 90% improvement in the loss of extension was achieved in the MCP joints of each finger. The mean percentage improvements were 54% and 38% in the PIP joints of the ring and the little fingers, respectively, indicating only fair results	Disease within previously operated sites	14% (5% with recurrence plus extension) over a mean follow-up of 4 years
Abe, 2004[26]	77	72 men and 5 women; average age was 62 years; average duration of disease was 5 years; 15 patients had involvement of knuckle pads; 20 had plantar fibrosis; and 58 had bilateral hand involvement	Case series–surgery involving radial side of hand	No recurrence or extension	50% had no recurrence or extension over a mean of 4 years of follow-up	Disease within previously operated sites	23% over a mean follow-up of 4 years
Citron, 2005[27]	79	63 men and 16 women; 12 with knuckle pads	Randomized clinical trial–fasciectomy	Full correction of contracture	96.2%	Any new nodule of disease in the operative field under the flaps	26.2% over 2 years of follow-up
Dias, 2006 [28]	1177	969 men and 208 women; mean age 63 years; 197 with bilateral disease	Survey–partial fasciectomy, open palm, dermofasciecto-my with skin graft	Full correction of contracture	58% of 229 patients with a mild MCP joint contracture had a full correction versus 28% of 264 patients with severe contractures of both the MCP and PIP joints	Reappearance of a contracture sufficient to require surgery, according to Hueston's tabletop test	15% had recurrent or persistent disease over a mean of 27 months of follow-up

Anwar, 2007[15]	109	All women; average age was 63 years	Case series–fasciectomy, fasciectomy and local flap, or dermafasciecto-my	Comparison of pre- and postoperative measurements made using a goniometer; and percentages of patients achieving full correction	Mean pre- and postoperative contractures for MCP joints were 35° and 1°, respectively. Mean preoperative contracture for PIP joints was 42°, and mean postoperative contracture was 7°. Full correction was 97% for MCP, 67% for PIP, and 100% for DIP	Disease within previously operated sites	22% (pooled for all procedures) over an average of 12 months of follow-up
Jurisic, 2008[29]	93	Mean age 58 years; mean duration of disease 10 years; bilateral hand involvement in 62 patients, ectopic lesions in 13 patients (9 Garrod's knuckle pads and 4 Ledderhose's disease)	Case series–partial fasciectomy	No recurrence or extension of disease	52% had extension, 42% had recurrence with extension, and 73% had recurrence over 7 years of follow-up (data presentation made it impossible to determine mutually exclusive outcomes)	Development of new Dupuytren's disease lesions, including the smallest palpable nodule irrespective of a presenting contracture, in the same area where fasciectomy had been performed	73% over a median of 7 years of follow-up
Ullah, 2009[30]	79	65 men and 14 women; mean age was 62.9 years; mean duration of disease was 6.1 years; mean contracture was 21° at the MCP joint and 59° at the PIP joint; 46 patients had bilateral disease	Randomized clinical trial–fasciectomy versus dermofasciectomy (firebreak skin graft)	Degree of contracture, its correction, and the range of movement at the MCP and PIP joints assessed immediately and 2 weeks after surgery	All the MCP contractures were corrected fully, whereas the PIP deformities were corrected to a mean of 6° of contracture in both groups	Recurrence of contracture of the PIP joint	12.2% (pooled for both procedures) over 3 years of follow-up
Kartik, 1963[31]	294	Bilateral involvement in 40 patients	Case series--aponeurectomy	Qualitative assessment with rating of excellent, good, or bad	79% of surgeries were rated as excellent; 16% as good; and 5% as bad	Nodes or fasciae appearing in the area of the operation	4.9% over up to 10 years of follow-up

MCP = metacarpophalangeal; PIP = proximal interphalangeal.

Table 1: Fasciectomy (including Surgical Aponeurectomy)

Citation	Number of Patients	Patient Characteristics	Study Design and Procedure	Correction of Contracture Definition	Correction Rate	Recurrence Definition	Recurrence Rate
Andrew, 1991[32]	46	38 men and 8 women; mean age was 65.5 years; mean duration of disease was 6.5 years	Prospective single treatment study--segmental aponeurectomy	Change in mean flexion contracture	At 12 months, MCP joint contracture decreased from 41°-1.1°, PIP joint contracture from 50°-22°, and total flexion deformity decreased from 61°-12.3°	The presence of a detectable disease in the operated ray	15.2% over 12 months of follow-up
De Maglio, 1996[33]	186 (124 evaluable for recurrence)	169 men and 17 women; mean age was 59 years; 21 had bilateral involvement; Tubiana-Michon stage was 1 for 20 patients, 2 for 41 patients, 3 for 36 patients, and 4 for 48 patients	Case series--aponeurectomy	Excellent was defined as complete extension, good as residual flexion ≤15°, fair as residual flexion >15°, and poor if no improvement in function	Postsurgical outcomes were 55.2% excellent, 33.8% good, 5.5% fair, and 5.5% poor	Occurrence of a nodule	24.1% over a mean follow-up of 33 months

MCP = metacarpophalangeal; PIP = proximal interphalangeal.

Table 1: Fasciotomy

Citation	Number of Patients	Patient Characteristics	Study Design and Procedure	Correction of Contracture Definition	Correction Rate	Recurrence Definition	Recurrence Rate
Rodrigo, 1976[34]	359 hands (135 available for follow-up for ≥2 years)	Pre-operative deficits in MCP extension were 27° for hands undergoing fasciectomy and 43° for hands undergoing fasciotomy; the respective values for PIP joints were 46° and 44°	Case series--fasciotomy and fasciectomy (fascial excision)	Changes from baseline in MCP and PIP joint extension	Postoperative gains in MCP extension at 2 months after surgery were 26° for hands undergoing fasciectomy and 35° for hands undergoing fasciotomy; the respective values for PIP joints were 19° and 1°	Recurrence of the disease in areas of the hand from which the fascia had been removed previously	63% of hands over ≥2 years of follow-up
Citron, 2003[35]	30	24 men and 6 women; mean age was 66.5 years; knuckle pads in 2 patients	Nonrandomized clinical trial--fasciotomy with transverse incision and direct closure or longitudinal incision and Z-plasty closure	Change from preoperative MCP flexion deformity	Fasciotomy decreased MCP flexion deformity from 35°-12° and fasciotomy plus Z-plasty decreased MCP flexion deformity from 28°-9°	The reappearance of Dupuytren's tissue in the operative field. This included isolated nodules, without contracture, but did not include extension beyond the operative field	33.3% (pooled for all procedures) over 2 years of follow-up
van Rijssen, 2006[36]	52	44 men and 8 women; mean age was 65 years; the mean preoperative TPED was 62°	Case series--percutaneous needle fasciotomy	Postoperative change from baseline TPED	Mean TPED overall immediately after surgery was 18°, a mean reduction of 77%. In the MCP joints, the mean reduction in TPED of 88%; and in the PIP joints, it was 46%. The TPED was decreased by 75% for the single PIP joint treated	TPED increased during follow-up of ≥30° compared with the immediate postoperative measurements	65% after 32 months of follow-up

MCP = metacarpophalangeal; PIP = proximal interphalangeal; TPED = total passive extension deficit.

Appendix A: Initial Search

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8

CHAPTER NINE:

SUMMARY AND GENERAL DISCUSSION

9

This thesis was primarily designed to compare limited fasciectomy (LF) to percutaneous needle fasciotomy (PNF) as treatment modalities for Dupuytren's Disease in a randomised fashion. The effect of these two treatments on the total passive extension deficit (TPED) was compared together with their complication rates, recurrence rates and overall patient satisfaction. Furthermore, we studied the effects of PNF for recurrent disease and performed a literature study on definitions of successful treatment and recurrence in Dupuytren's disease.

Chapter one is an introduction to the subject, defines the aims of the thesis and gives an outline.

Chapter two gives, based on the available literature by the time it was written, an overview of different treatment modalities for Dupuytren's disease. One of the most important conclusions is that, although more and more treatment options seem to be available, very few comparative studies have been published.

In **chapter three**, the results of a pilot study on percutaneous needle fasciotomy are presented. This study was designed to determine whether in our hands, PNF was an effective treatment for Dupuytren's disease, and if results were comparable to those reported by others. For this purpose, the results of 74 consecutive percutaneous needle fasciotomies for Dupuytren's contracture were studied. Pre-operative and postoperative total passive extension deficit was measured. Patients were seen at the outpatient clinic after a mean of 33 months for final follow-up. Extension deficit and sensibility were measured and flexor tendon function assessed. Recurrence, defined as an increase of 30º of TPED or more compared to the immediate postoperative measurement, and complications were also noted. Immediate outcome was excellent with an average improvement of 77%. After 32 months, we were able to review 55 rays (74%). The recurrence rate was 65%. Two patients experienced a slightly diminished sensibility on one side of the finger. There were no flexor tendon injuries and full active flexion in all treated digits was possible. Comparison to other studies showed that our immediate results were very good, and recurrence rates were comparable to those of other authors.

Chapter four is the first chapter that extensively describes the design and implementation and short-term (six weeks) outcome of our randomized controlled study on percutaneous needle fasciotomy versus limited fasciectomy.

This randomized controlled trial was designed to compare percutaneous needle fasciotomy (PNF) with limited fasciectomy (LF) with regard to outcome, number of complications, recovery, and patient satisfaction.

One hundred and sixty-six rays of 117 hands in 113 patients were treated: 88 by PNF and 78 by LF. Total passive extension deficit (TPED) improvement at 1 week and at 6 weeks following treatment were the primary outcome parameters; patient satisfaction, hand-function recovery, and complication rate were secondary outcome parameters. The Disabilities of the Arm, Shoulder, and Hand questionnaire (DASH) was used to measure disabilities of the upper extremity before and after treatment and all adverse effects and complications were recorded.

Overall TPED improvement was greatest at 6 weeks. In the PNF group TPED improved by 63% versus 79% in the LF group; this difference was statistically significant. These results were comparable to those reported by others. Results at the proximal interphalangeal joint were worse than those at the metacarpophalangeal and distal interphalangeal joints for both the PNF and LF groups. The rays classified before surgery as Tubiana Stages I and II showed no difference between these treatments, but for rays higher than Stage II LF clearly was superior to PNF as a treatment modality. The rate of major complications in the LF group was 5% (one nerve injury) versus 0% in the PNF group. Patient satisfaction was almost equal but direct hand function after treatment was considerably better in the PNF group, and the degree of discomfort that PNF treated patients experienced was lower. This was underscored by the Disabilities of the Arm, Shoulder, and Hand scores in the PNF group, which were significantly lower than those in the LF group at all time points measured.

From this study it was concluded that in cases with a TPED of 90° or less PNF is in the short run a good treatment alternative to LF for treatment of Dupuytren's disease. This study was the start of an exciting study with five years follow-up.

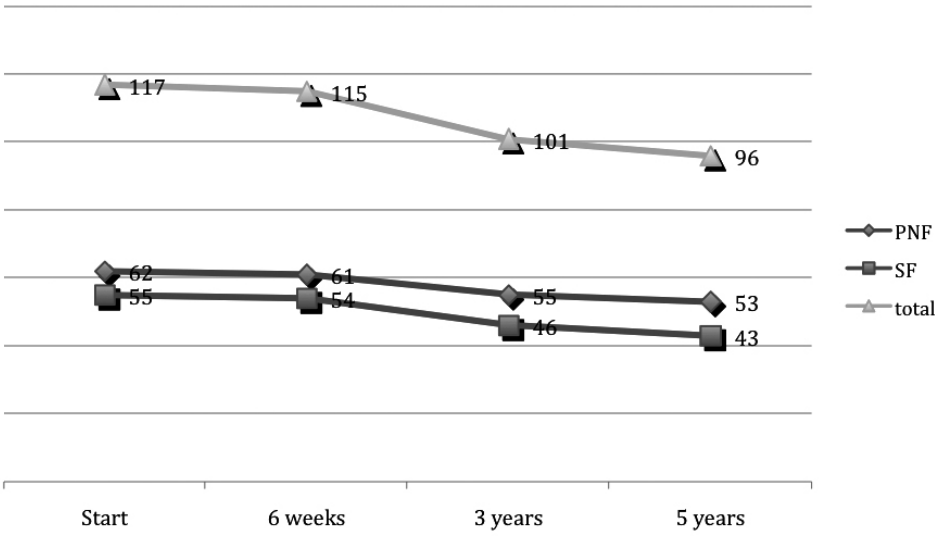
In **chapter five**, the 3-years follow-up results of the randomized clinical trial are presented. In this study we focussed primarily on recurrence, defined as an increase in TPED of at least 30° as compared to the six weeks results. This interim analysis was planned to be able to compare especially the PNF results with those previously reported (Foucher 1992, Van Rijssen 2006a).

A total of 115 hands in 111 patients were available for follow-up at 3 years (8 patients with 8 hands were lost to follow-up). This intermediate analysis revealed a recurrence after PNF in 64% of cases. These results were comparable to those of the authors just mentioned. Recurrence after PNF occurred significantly more frequent (p=0.005) than after LF (9%). We also found that younger patients develop recurrent disease sooner after treatment for Dupuytren's disease, independent of the treatment they received. Satisfaction with the results of treatment was high in both groups, but in the LF group higher than in the PNF group. Nevertheless, patients who had previously undergone PNF and developed recurrence were keen to have their recurrences treated by PNF again.

Chapter six delineates the 5-year results of the study. From the population of patients described in Chapters 3 and 4, 93 patients with 96 affected hands were still available for study. After 5 years, the recurrence rate in the PNF group was with 84.9% again significantly higher than that of the LF group (20.9%), $p < 0.001$, and occurred significantly sooner in the PNF group ($p = 0.001$). Higher age at time of treatment was again found to diminish the risk of recurrent disease, p=0.005. We were unable to prove that diathesis characteristics influenced recurrence. Satisfaction was high in both groups, but in the LF group significantly higher than in the PNF group. Nevertheless, many patients (53%) chose to have their recurrence treated by PNF.

Comparison of the results on PNF and LF with available results of treatment with Clostridium Histolyticum derived Collagenase revealed that we achieved better long term results with LF than were obtained with collagenase (Hurst 2007, Hurst 2009, Watt 2010). A single treatment with PNF, however, seems to be somewhat inferior to up to three injections with collagenase. Recurrence rates of collagenase therapy are comparable, if not worse compared to our PNF results after 5 years.

The graph below shows the number of hands in the study at commencement, at 6 weeks, 3 years and 5 years.



Graph 1: Number of hands in the study at the start, after 6 weeks, 3 years and at 5 years.

Chapter seven is the first publication of results of PNF for recurrent disease.

From the previous studies, 30 patients with recurrent disease, with a total of 40 affected rays in 30 hands, were studied. The mean follow-up (FU) was 4.4 years. Primary outcome measure were Total Passive Extension Deficit Reduction, and interval to a second recurrence, defined as an increase of more than 30° compared to the result at the end of previous treatment.

Immediate results were good: TPED reduction was 76%. PNF was especially effective for the MCP joint, with an average reduction of 93%, whereas average reduction in the PIP joint was 57%. Fifty percent of cases did not develop a secondary recurrence during follow-up. The other fifty percent of patients did, and recurrence was treated within 1.4 years on average after PNF. By means of PNF, LF was postponed on average 2.9 years starting from the initial treatment for Dupuytren's disease.

From this study we concluded that PNF can effectively be applied for recurrent disease and 50% of cases remain free of recurrence for a mean of 4.4 yrs. If a secondary recurrence occurs, it does so relatively early after treatment: patients must therefore be willing to accept this uncertainty in the context of the advantages of PNF, such as fast recovery, low complication rate and minimal invasiveness.

Chapter eight concerns a systematic review about the success of different surgical approaches to the treatment of Dupuytren's contracture, focusing on recurrence and considering the various criteria used to define successful treatment and recurrence.

A literature search was carried out in January 2011 using the terms "dupuytren's" AND ("fasciectomy" OR "fasciotomy" OR "dermofasciectomy" OR "aponeurotomy" OR "aponeurectomy") and limited to studies in English.

The search returned 218 papers, of which 21 had definitions, quantitative results for contracture correction and recurrence, and a sample size of at least 20 patients. Definitions for correction of contracture and recurrence varied greatly among papers and were almost always qualitative. Percentage of patients who achieved correction of contracture (i.e., responder rate) when evaluated at various times after completion of surgery ranged from 15% to 96.2%. Recurrence rates ranged from 4.9% to 73%. Review of these studies underscored the difficulty involved in comparing correction of contracture and recurrence rates for different surgical interventions because of differences in definition and duration of follow-up.

This study showed us that clearly defined objective definitions for correction of contracture and for recurrence are needed for more meaningful comparisons of results achieved with different surgical interventions.

Therefore, the principle conclusions from this thesis that compared the short and long term outcome of LF and PNF are that

1. PNF is best suitable for elder patients and for those willing to accept the drawback of a possible early recurrence and want to benefit of advantages such as fast recovery, low complication rate and minimal invasiveness.

2. LF still is a very reliable treatment modality, with major advantage that recurrences do not occur as rapidly as following PNF. Its major disadvantage is that it has a much longer rehabilitation period. Since recurrence is age-related, LF may be a better treatment choice for the younger age group.

3. PNF can also be attempted in case of recurrent disease. It will "cure" half of the patients, and at least postpones more invasive treatment regimens for the other half of patients.

Due to the fact that clearly defined definitions in literature on treatment of Dupuytren's disease are lacking, comparison between studies is difficult and less reliable than it possibly could be.

The strongholds of this research project were its randomised controlled nature and the fact that beforehand a pilot study was performed to find out if our treatment results were comparable to those of others. By doing all this we feel that we have contributed significantly to the evidence based scientific knowledge of treating patients with Dupuytren's Disease.

However, when looking back we also see a number of shortcomings and mistakes of this project, which we want to spell out in detail to help successors in the design of future studies.

Randomisation

Patients were randomised in the two treatment groups by having a secretary at random pull a sealed envelop containing a note saying either LF or PNF from a box. In a review study by Becker and Davis this method was termed "pseudo-randomisation".

Although we cannot agree with this term, for future studies we will use a computer based randomisation method (Kang 2008, Becker and Davis 2011).

Treatment

We were relatively inexperienced in the use of PNF when we embarked on this journey. Therefore we performed a pilot study to investigate if our results were comparable to those of others. And indeed these results were similar. Therefore we felt comfortable to start the RCT. Now, with almost 10 years of experience in PNF we have become a bit more daring and are not hesitant to apply PNF on cords in the vicinity of the neurovascular bundles. We fully agree will Eaton (2011) that this is safe as long as only the skin is numbed. Our Tubiana 3 and 4 results these days are better than those of our RCT (unpublished data).

During the RCT we inflicted injury to a nerve during LF. It was the ulnar nerve of the long finger in a case in which only the ring finger was affected: the nerve was pulled up together with surrounding fat tissue that was still connected to the cord. This injury was an act of inattention and should have been prevented.

Patient questionnaires

For the registration of events in the first 6 weeks after treatment in the RCT we asked all patients to fill out a Dutch translation of the DASH questionnaire and the Short Form (SF)-36. The Dutch translation of the DASH questionnaire is a validated instrument that can be used to score disabilities of the upper extremity during daily activities (Hunsaker, 2002 Veehof 2002). This questionnaire consists of 30 items that address disability and symptoms of the upper extremity on a scale from 0 to 5. The scores are added and transformed into a 100-point scale. The lower the score, the less disability is experienced. The SF-36 is a general health survey with 36 questions. Functional health and well-being scores as well as psychometrically-based physical and mental health summary measures are taken. (Ware and Sherbourne 1992) It consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale.

From the SF-36, it was already known in 1999 that response rates in patients above 65 years old and in patients with cognitive or physical disabilities are too low to be used (Andresen 1999). When we designed our protocol we did not know this, but during the study we became bluntly aware of this shortcoming, since the answers the patients gave were inconsistent. In our study the mean age at commencement was 63 years old. In the description of our results, we decided to discard all data on the SF-36 because of the high rate of invalid filled-out questionnaires.

In the DASH scoring system, at least 27 of 30 items must be scored to give a reliable outcome. The DASH score questionnaires at the start of the study and in the immediate postoperative period were filled in satisfactory by most patients. However, as time progressed during the study, many patients appeared to be unwilling to fill out the long questionnaire over and over again. This resulted in too high failure rates, which made the DASH questionnaire useless. In 2006, the QuickDASH was developed. This is a much shorter questionnaire with reliable outcome in Dupuytren's disease (Budd 2011). If this had been available at the start of our study, this would have been a much better alternative.

Another shortcoming of DASH is that it is not very specific for the investigations of hand problems. For future trials, alternatives worth considering are Patient Evaluation Measure (PEM), Michigan Hand outcomes Questionnaire (MHQ), Patient Rated Wrist/Hand Evaluation (PRWHE) and the very recently presented Southhampton's Dupuytren Scoring Scheme (Bindra 2003, Changulani 2008,Van de Ven-Stevens 2009,Warwick, recently submitted for publication 2011)

All patients were asked to fill in the questionnaires at home every week after the treatment, until 6 weeks post-treatment. Two patients failed to fill in any questionnaires and for this reason we excluded them for further follow up. We now feel that this was unnecessary: we could have left them in the trial for longer-term follow up.

Follow-up investigations

Most, but not all follow-up investigations were conducted by an independent investigator. In future studies this should always be done by a person not involved in the study.

PNF for recurrent disease

Our study on PNF for recurrent disease is not of a flawless design. Obviously, the group of patients treated by PNF for recurrent disease we reviewed for our study on the application of PNF for recurrence was quite small (30 patients). This made it difficult to prove if any of the known risk factors had an influence on the timing of a second recurrence. Possibly, there was also a selection bias (patients were not randomly assigned to either PNF or LF), which may have caused the outcomes of these patients to be more favourable. However, as this is the first study on the effectiveness and long-term outcome of PNF, we feel that it is still very worthy of publication.

Definition of recurrent disease

As mentioned in all chapters on recurrence rates, "recurrence" is an ill-defined entity in Dupuytren's disease. This makes comparison to previously reported studies almost impossible. The most commonly used definition is "reappearance of Dupuytren's tissue in a previously operated zone" (McFarlane 1990, Becker 2010). This definition of recurrence could not be used in this study, since in PNF no tissue is removed. Nodules that are present before the procedure often remain unchanged or at best soften. The cords are divided but over time seem to reconnect. For this study we therefore used a more indirect definition for recurrence: an increase of the Total Passive Extension Deficit of 30º or more in a ray compared to the result at 6 weeks post treatment. This measure is reproducible and clinically more significant than the other definitions, since it is progressive contracture that ultimately leads to reintervention, while reappearance of Dupuytren's tissue itself does not necessarily impair hand function or forms the indication for treatment. We chose a worsening of digital extension of 30º because this corresponds to Hueston's tabletop test and since it is the minimal contracture that makes a patient eligible for surgery at our treatment centre.

However, many of the latest studies on Dupuytren's disease, such as the ones on Clostridium Histolyticum derived Collagenase, use a very different definition (Hurst 2009, Watt 2010, Gilpin 2010). All collagenase studies look at the effect of treatment at each joint individually. The treatment is named "clinically successful" when correction of the deformity is to within 0-5˚ of full extension. Up to three injections at 30

days' intervals are allowed to reach this endpoint. We find this way of presenting data somewhat misleading. The treated MCP joint can remain good, while the PIP joint is contracting. This still may impair the patient's hand function, and that is what ultimately defines the success of the treatment of Dupuytren's disease. Therefore, it is our opinion that one should not look at one joint, but at least at a complete ray. Much can be said about looking at a whole hand altogether, because Dupuytren's disease is a diffuse disease that is not restricted by any imposed anatomic border.

Moreover, in studies on recurrence after treatment with collagenase, only the "clinically successfully" treated patients are taken into account in analyzing recurrence rates (Hurst 2009, Watt 2010, Xiaflex press release 2011). This is obviously a deceiving way to present one's achievement. For instance, in recently published data by Xiaflex, only 623 of 1568 treated joints reached clinical success (39,7%), 945 did not reach the 'success' endpoint. After 3 years, 217 of former had recurrence. They present a recurrence rate of 39,7 % (217/623), while the recurrence rate of the other subgroup remains unknown, which obviously creates a bias.

In our study, all treated rays of one hand fell out of the study when one ray on this hand showed signs of recurrence to prevent bias. This is another shortcoming of our design: we could have followed each ray individually.

The issues on definitions of treatment success and recurrence bothered us very much, which urged us to write a review study on the subject. This review was performed in January 2011. We feel that if we would have considered these issues in more detail at the start of the randomized study, we might have made other choices, such as presenting our data in a different way to make comparison with for example collagenase studies easier.

FUTURE PERSPECTIVES

It would be much more reliable if every study on Dupuytren's disease would use the same definition of recurrence, which should be applicable to every treatment modality. We recommend using the following definition of recurrence: an increase of TPED of a fixed number of degrees (20 or 30°) compared to the immediate postoperative measurements in the ray previously treated. Extension should be defined as an increase of 20-30° TPED in a ray outside the area previously treated. This way, extension and recurrence are clinically relevant for the patient, for hand function deteriorates when Hueston's tabletop test is positive.

Many new exciting techniques are being developed in treatment of Dupuytren's disease. Very recently, new work was published on a combination of extensive percutaneous aponeurotomy and lipografting (Hovius 2011). The authors found the results of regular aponeurotomy disappointing, due to early recurrences, and decided to add fat subcutaneously as interposition between skin and fascia, but also to restore the relative deficiency of subcutaneous fat. Short-term results are very promising: in 50 patients who were treated, mean improvement ranged from 56.4% to 114%, and 88% of patients reached Tubiana stage I after treatment. It will be exciting to hear long-term results, which are not available at this moment.

Also, many studies are being performed on treatment with collagenase (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010). It would be very interesting to compare collagenase with other treatment regimens on Dupuytren's Disease to see whether this is truly a good alternative. In the near future, more data will probably become available on long-term data en effectiveness.

In Germany, radiotherapy is by some employed in early stage Dupuytren's disease (Betz 2010).

However, more research should be done, not only on effectiveness and safety of these techniques, but more importantly, to compare these treatment regiments in equal groups in a randomised controlled fashion. As said before, comparing current literature would be easier if the same definitions of recurrence and extension would be used in all studies.

Interestingly, we were the first to prove that higher age at time of treatment diminish-

es the risk of recurrent disease. No other studies have proven this before. It would be interesting to see whether this can be re-confirmed in larger studies as well, and to see whether a different advice on treatment should be given to various age groups.
Another unanswered question remains what the role is of postoperative hand therapy and splint therapy in the treatment of DD. Although routine splinting after fasciectomy and dermofaciectomy appears not to improve disability and range of motion, there might be a place for splinting and hand therapy after less-invasive treatments, such as PNF, collagenase, of radiotherapy (Meinel, unpublished data, Jerosch-Herold 2011).
Last but not least, very little literature is available on treatment of recurrent disease, independent which technique is used. Recurrences are very common, no matter which initial treatment modality is used. It would be very interesting to see which treatment, if any, is superior in treating recurrent disease, whether different age groups would have different results after treatment for recurrent disease and whether splinting or hand therapy would be of any benefit after recurrence treatment.
We have proved that PNF is a well-worthy alternative in the treatment of recurrences. Further studies with larger groups of patients are needed to define its specific indications. And hopefully, we will be able to compare the results of PNF and other treatment regimens for recurrent disease in the future.

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CHAPTER TEN:

SAMENVATTING EN ALGEMENE DISCUSSIE

10

Het onderzoek dat is verzameld in dit proefschrift is er vooral op gericht om op gerandomiseerde wijze de selectieve fasciëctomie (SF) en de percutane naald fasciotomie (PNF) te vergelijken als behandelingsmethoden voor de ziekte van Dupuytren. Het effect van deze twee behandelingen op het totale passieve extensie deficit (TPED) werd vergeleken, evenals complicaties, recidief en de algemene tevredenheid van de patiënt op de korte, middellange (3 jaar) en lange (5 jaar) termijn. Voorts zijn de effecten van PNF onderzocht op het optreden van een recidief en is een tweetal literatuurstudies verricht. De eerste literatuurstudie geeft een resumé van de voors en tegens van alle beschikbare behandelingsmogelijkheden en de tweede bevat een systematische review van de definities van "succesvolle behandeling" en "recidief" bij de ziekte van Dupuytren. Het onderstaande geeft een samenvatting van de bevindingen, analyseert deze bevindingen kritisch en doet aanbevelingen voor toekomstig onderzoek naar de ziekte van Dupuytren.

Hoofdstuk één omvat de inleiding op het onderwerp: in dit hoofdstuk worden de doelstellingen van het proefschrift beschreven.

Hoofdstuk twee geeft, op basis van de literatuur beschikbaar in 2008-9, een overzicht van de verschillende behandelingsmogelijkheden voor de ziekte van Dupuytren. Een van de belangrijkste conclusies is dat, hoewel steeds meer en meer behandelingsopties beschikbaar zijn, zeer weinig vergelijkende studies zijn gepubliceerd.

Hoofdstuk drie presenteert de resultaten van de pilotstudy naar percutane naald fasciotomie.

Deze studie werd ontworpen om te laten zien dat wij in staat waren PNF op een effectieve manier uit te voeren en dat de resultaten vergelijkbaar waren met die uit de literatuur. Hiervoor werden de resultaten van 74 opeenvolgende percutane naald fasciotomiën bestudeerd. Het preoperatieve en postoperatieve extensietekort werd gemeten. De patiënten werden poliklinisch gezien na een gemiddelde van 33 maanden voor de laatste follow-up. Verergering van het extensiedeficit werd gemeten, de sensibiliteit werd onderzocht en de flexorpeesfunctie beoordeeld. Het ontstaan van een recidief, gedefinieerd als een toename van het extensiedeficit van 30 º of meer in vergelijking met de directe postoperatieve meting, werd genoteerd, evenals de eventuele compli-

caties. Het onmiddellijke resultaat was uitstekend met een gemiddelde verbetering van het extensietekort van 77%. Na 32 maanden werden 55 stralen teruggezien voor follow-up (74%). Het recidiefpercentage was 65%. Twee patiënten ervoeren licht verminderde unilaterale sensibiliteit. Er waren geen buigpeesletsels en volledige actieve flexie was mogelijk in alle behandelde vingers. Vergelijking met andere studies toonde aan dat onze directe resultaten zeer goed waren, en de recidiefkans in onze studie vergelijkbaar was met die van andere auteurs.

Hoofdstuk vier beschrijft uitgebreid het ontwerp, de uitvoering en de korte termijn resultaten (na zes weken) van de gerandomiseerde gecontroleerde vergelijkende studie naar percutane naald fasciotomie en selectieve fasciëctomie

Honderd zesenzestig stralen van 117 handen in 113 patiënten werden behandeld: 88 middels PNF en 78 middels SF. De verbetering van het extensiedeficit op 1 week en 6 weken na de behandeling waren de belangrijkste uitkomstmaten, de tevredenheid van patiënten, het handfunctie herstel en het aantal complicaties zijn secundaire uitkomst parameters. De handicap van de arm, schouder en hand vragenlijst (DASH scorelijst) werd gebruikt om symptomen en functionele beperkingen in de bovenste extremiteit gedurende de week voorafgaand aan de behandeling te meten en na 1 en 6 weken na de behandeling. Alle bijwerkingen en complicaties werden geregistreerd.

Algehele verbetering van het extensietekort was het grootst na 6 weken. In de PNF groep verbeterde deze met 63% tegenover 79% in de SF-groep, dit verschil was statistisch significant. Deze resultaten waren vergelijkbaar met die welke door anderen werden gepubliceerd. Resultaten van de PIP gewrichten waren slechter dan die van de MCP en DIP gewrichten in zowel de PNF en SF groep. De stralen welke preoperatief geclassificeerd werden als Tubiana stadium I en II toonden geen verschil tussen deze behandelingen, maar voor stralen hoger dan stadium II was SF duidelijk superieur. In de SF-groep was de kans op ernstige complicaties 5% (één zenuwbeschadiging) versus 0% in de PNF groep. De tevredenheid van patiënten was vrijwel gelijk, maar de directe handfunctie na de behandeling was aanzienlijk beter in de PNF groep, en de mate van ongemak welke met PNF behandelde patiënten ervoeren lag lager. Dit werd onderstreept door de DASH scores in de PNF groep, die beduidend lager waren dan die in de SF-groep op elk gemeten tijdstip (behalve preoperatief).

Uit deze studie kan worden geconcludeerd dat in gevallen waarbij het extensietekort kleiner of gelijk is aan 90°, PNF een goede behandelingsalternatief is voor SF met betrekking het directe behandelresultaat. Deze studie was het begin van een onderzoek met vijf jaar follow-up.

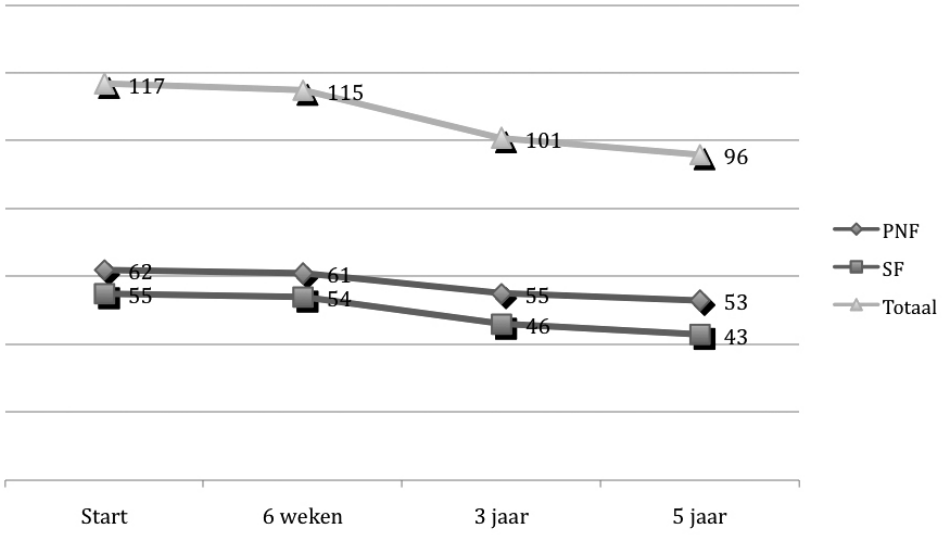
In hoofdstuk vijf worden de 3-jaar follow-up resultaten van de gerandomiseerde klinische studie gepresenteerd. In deze studie hebben we ons in de eerste plaats gericht op recidief, gedefinieerd als een toename van de TPED van ten minste 30° ten opzichte van de resultaten zes weken postoperatief. Een totaal van 115 handen bij 111 patiënten waren beschikbaar voor follow-up na 3 jaar (8 patiënten met 8 handen waren lost to follow-up). Deze tussentijdse analyse toonde een recidief na PNF in 64% van de gevallen. Recidieven na PNF kwamen significant vaker voor dan na SF (9%) ($p = 0,005$). Tevens bleek dat jongere patiënten sneller een recidief ontwikkelen na behandeling voor de ziekte van Dupuytren, onafhankelijk welke behandeling die zij ontvingen. Tevredenheid met de resultaten van de behandeling was hoog in beide groepen, maar de SF-groep scoorde hoger dan de PNF groep. Toch kozen patiënten die eerder PNF hadden ondergaan die een recidief ontwikkelden velen male opnieuw PNF als behandeling voor het recidief.

Hoofdstuk zes schetst de 5-jaars resultaten van de studie. Van de oorspronkelijke populatie van patiënten beschreven in de hoofdstukken 3 en 4, waren 93 patiënten met 96 handen beschikbaar voor onderzoek. Na 5 jaar is het recidiefpercentage in de PNF groep met 84,9% aanzienlijk hoger dan het percentage in de SF-groep (20,9%), $p < 0,001$, en traden recidieven veel eerder op in de PNF groep ($p = 0,001$). Hogere leeftijd ten tijde van de behandeling werd opnieuw van significante invloed bevonden op het ontstaan van een recidief, waarbij hogere leeftijd ten tijde van de behandeling protectief is, $p = 0.005$. Er werd geen bewijs gevonden dat Dupuytren's diathese de recidiefkans beïnvloedt. De tevredenheid was hoog in beide groepen, maar in de SF groep significant hoger dan in de PNF groep. Toch kozen veel patiënten (53%) om hun recidief opnieuw te laten behandelen middels PNF.

Vergelijking van de resultaten van PNF en SF met beschikbare resultaten van de behandeling met van Clostridium Histolyticum afkomstig collagenase bleek dat op lange termijn de resultaten van SF beter zijn dan die van collagenase. Een enkele behande-

ling met PNF, echter, lijkt enigszins inferieur aan drie injecties met collagenase. Recidiefkans na behandeling met collagenase is vergelijkbaar, zo niet slechter dan de PNF recidiefkans na 5 jaar.

De onderstaande grafiek toont het aantal handen in de studie ten tijde van aanvang, na 6 weken, 3 jaar en 5 jaar.



Grafiek 1: Aantal handen in de studie aan de start, na 6 weken, 3 jaar en na 5 jaar.

Hoofdstuk zeven presenteert de korte en lange termijn resultaten van de PNF bij de behandeling van recidief Dupuytren.

Dertig patiënten met een recidief uit de RCT, met een totaal van 40 stralen in 30 handen, werden bestudeerd. De gemiddelde follow-up na PNF was 4,4 jaar. Primaire uitkomstmaten waren vermindering van het TPED, en interval tot een tweede recidief, waarbij "recidief" gedefinieerd werd als een stijging van meer dan 30° van het TPED per straal ten opzichte van het resultaat op het einde van de vorige behandeling.

Onmiddellijke resultaten waren goed: de vermindering van het extensiedeficit bedroeg 76%. PNF was vooral effectief ter plaatste van het MCP gewricht, met een gemiddelde reductie van het deficit van 93%, terwijl de gemiddelde daling van het deficit in het PIP gewricht 57% bedroeg. Vijftig procent van de gevallen bleef tijdens de follow-up

vrij van een tweede recidief. De overige vijftig procent van de patiënten kreeg opnieuw een recidief, welke na gemiddeld 1.4 jaar werd behandeld. Door middel van twee keer PNF, kon een meer invasieve behandeling zoals SF gemiddeld 2,9 jaar uit gesteld worden.

Uit deze studie valt te concluderen dat PNF ook effectief kan worden toegepast voor recidief Dupuytren: 50% van de gevallen bleef vrij van recidief voor een gemiddelde van 4,4 jaar. Als er een tweede recidief optreedt, gebeurt dit relatief vroeg na de behandeling: patiënten moeten dus bereid zijn om deze onzekerheid te aanvaarden in het kader van de voordelen van PNF, zoals snel herstel, weinig complicaties en een minimale invasiviteit.

Hoofdstuk acht geeft een systematische review van de resultaten van verschillende chirurgische behandelingen voor de ziekte van Dupuytren, gericht op de verschillende criteria die werden gebruikt om de "het succes van een behandeling" en de definitie van een recidief te definiëren. Deze studie werd geïnitieerd in nauwe samenwerking met de Amerikaanse Collagenase Study Group. literatuuronderzoek werd uitgevoerd in januari 2011 naar het gebruik van de termen "Dupuytren" EN ("fasciectomy" OF "fasciotomie" OF "dermofasciectomy" OF "aponeurotomy" OF "aponeurectomy") waarbij werd beperkt tot studies in het Engels.

Deze zoekopdracht leverde 218 artikelen op, in slechts 21 gevallen bleken duidelijke definities van de uitkomst parameters te zijn gebruikt, werden kwantitatieve resultaten vermeld voor correctie van de contractuur en recidief, en werden ten minste 20 patiënten beschreven. Definities voor behandelingsresultaat en recidief varieerden sterk tussen de verschillende studies en waren bijna altijd kwalitatief. Het percentage patiënten dat een correctie van de contractuur bereikte na een operatie varieerde van 15% tot 96,2%. Recidiefpercentages liepen uiteen van 4,9% tot 73%. Deze evaluatie onderstreepte opnieuw de variabiliteit van de uitkomstmaten, de definities en de duur van de follow-up, welke een vergelijking van ons werk met dat van anderen ook al had belemmerd. Deze studie toont aan dat duidelijke objectieve definities voor de behandelingsresultaten en recidieven nodig zijn voor een zinvolle vergelijking van de resultaten van verschillende chirurgische ingrepen.

De belangrijkste conclusies van dit proefschrift luiden als volgt:

1. PNF is het meest geschikt voor oudere patiënten en voor degenen die bereid zijn om het nadeel van een mogelijk vroegtijdig recidief te aanvaarden, en voor hen die willen profiteren van voordelen zoals snel herstel, lage kans op complicaties en een minimale invasiviteit.

2. SF is nog steeds een zeer betrouwbare behandelingsmodaliteit, met als het grote voordeel dat recidieven minder snel en minder vaak optreden dan na PNF. Het grote nadeel is dat het een veel langere revalidatie periode kent. Omdat de kans op het ontstaan van een recidief leeftijdsgebonden is, is SF mogelijk een betere behandelingskeuze voor de jongere leeftijdsgroep.

3. PNF kan ook worden uitgevoerd in het geval van recidiverende ziekte. Het zal de helft van de patiënten "genezen", en op zijn minst stelt het meer invasieve behandelingen uit voor de andere helft van de patiënten.

4. Doordat duidelijk omschreven definities in de literatuur over de behandeling van de ziekte van Dupuytren ontbreken, zijn vergelijkingen tussen de verschillende studies moeilijk te maken.

De waarde van dit proefschrift ligt in de gerandomiseerde vergelijking van de SF met PNF, en het feit dat voor aanvang van de RCT een pilotstudy werd uitgevoerd om te testen of onze behandelingsresultaten vergelijkbaar waren met die in andere studies. Daarnaast hebben wij als eerste onderzocht of PNF effectief is in het geval van recidiverende ziekte. Op deze wijze is een bijdrage geleverd aan de evidence-based wetenschappelijke kennis van de behandeling van patiënten met de ziekte van Dupuytren.

Echter, terugkijkend zien we ook een aantal tekortkomingen en fouten van dit project. Hiervan geven wij een gedetailleerde beschrijving om deze te voorkomen bij eventuele toekomstige studies.

Randomisatie

Patiënten werden gerandomiseerd in de twee behandelingsgroepen door het willekeurig trekken van een verzegelde envelop met daarin een briefje met hetzij SF, hetzij PNF. In een recente studie van Becker en Davis werd deze methode aangeduid als "pseudo-randomisatie '. Hoewel we het niet eens met deze term, zullen we voor toekomstige studies gebruik maken van een computergestuurde randomisatie (Kang 2008, Becker en Davis 2011).

Behandeling

Aan het begin van de studie waren we relatief onervaren in het gebruik van PNF. Derhalve hebben we een pilotstudy verricht om te onderzoeken of onze resultaten vergelijkbaar waren met die van anderen. En inderdaad waren deze resultaten vergelijkbaar, dus voelden wij ons gesterkt in het starten van een gerandomiseerde studie.

Nu, met bijna 10 jaar ervaring met PNF hebben wij meer durf en aarzelen niet om PNF toe te passen in de buurt van de neurovasculaire bundels. We hebben ervaren dat dit veilig is, zolang alleen de huid is verdoofd. Het is zeer goed mogelijk dat onze huidige resultaten in het geval van Tubiana stadium 3 en 4 beter zijn dan die van onze RCT door agressievere therapie.

Tijdens de RCT werd één zenuw beschadigd tijdens het verrichten van een SF. Het was de ulnaire zenuw van digitus 4 in een geval waarbij alleen deze vinger was aangetast: de zenuw werd omhoog getrokken, samen met het omliggende vetweefsel. Dit letsel werd veroorzaakt door onoplettendheid en had moeten worden voorkomen.

Patiënt vragenlijsten

In de eerste 6 weken na de behandeling in de RCT vroegen we alle patiënten een Nederlandse vertaling van de DASH vragenlijst en de Short Form (SF) -36 in te vullen. De Nederlandse vertaling van de DASH vragenlijst is een gevalideerd instrument dat gebruikt kan worden om een functionele beperking van de bovenste extremiteit te scoren (Hunsaker 2002, Veehof 2002). Deze vragenlijst bestaat uit 30 items die betrekking hebben op invaliditeit en symptomen van de bovenste ledematen op een schaal

van 0 tot 5. De scores worden opgeteld en omgezet in een 100-punts schaal. Hoe lager de score, hoe minder beperkingen ervaren worden. De SF-36 is een gezondheidsenquête met 36 vragen. Met behulp van deze vragenlijst wordt de kwaliteit van leven gemeten. (Ware en Sherbourne 1992) De SF-36 bestaat uit acht scores, die berekend worden door een gewogen som te bereken van de vragen in één sectie. Deze wordt vervolgens omgezet in een 0-100 schaal.

Van de SF-36 was in 1999 al bekend dat de respons bij patiënten ouder dan 65 jaar en bij patiënten met een cognitieve of fysieke handicap te laag is om te worden gebruikt (Andresen 1999). Deze bevindingen zijn niet meegenomen bij het ontwerp van het protocol, maar tijdens de studie bleek deze tekortkoming, doordat de antwoorden die de patiënten gaven inconsistent waren. In onze studie was de gemiddelde leeftijd bij aanvang 63 jaar oud. In de beschrijving van onze resultaten hebben we besloten om alle gegevens van de SF-36 niet te gebruiken gezien het hoge percentage van ongeldig ingevulde vragenlijsten.

In het DASH score systeem moeten ten minste 27 van de 30 items worden gescoord om een betrouwbaar resultaat te geven. De DASH-score vragenlijsten aan het begin van de studie en in de directe postoperatieve periode werden door de meeste patiënten correct ingevuld. Echter, naarmate de tijd vorderde tijdens de studie, bleken slechts weinig patiënten bereid de lange vragenlijst keer op keer in te vullen. Dit resulteerde in een te hoge uitval, waardoor de DASH vragenlijst nutteloos was. In 2006 werd de QuickDASH ontwikkeld. Dit is een veel kortere vragenlijst met een betrouwbaar resultaat bij de ziekte van Dupuytren (Budd 2011). Als deze beschikbaar was geweest aan het begin van onze studie, zou dit een veel beter alternatief zijn geweest.

Een andere tekortkoming van de DASH scores is dat ze niet erg specifiek zijn voor handproblematiek. Voor toekomstige studies, zijn de PEM, MHQ, PRWHE en de zeer recent gepresenteerde Southhampton's Dupuytren Scoring Scheme en URAM scoring systems alternatieven die het overwegen waard zijn (Bindra 2003, Changulani 2008, Van de Ven-Stevens 2009, Warwick, onlangs ingediend voor publicatie 2011, Beaudrieul 2011)

Alle patiënten werd gevraagd om de vragenlijsten thuis in te vullen elke week na de behandeling, tot 6 weken na de behandeling. Twee patiënten vulden deze vragenlijst in het geheel nooit in en om deze reden werden ze uitgesloten voor de verdere follow-up. We hebben nu het gevoel dat dit niet nodig was: we hadden ze beter voor de langere termijn follow-up in de studie kunnen laten.

Follow-up onderzoek

Een onafhankelijk onderzoeker verrichtte de meeste, maar niet alle follow-up onderzoeken. In toekomstige studies zou dit altijd verricht moeten worden door een persoon die niet betrokken is bij de studie.

PNF in het geval van recidief

De studie naar de resultaten van PNF in het geval van recidief Dupuytren is niet perfect ontworpen. Uiteraard was de grootte van de groep vrij klein, omdat deze alleen bestond uit patiënten van onze RCT met een recidief (30 patiënten). Dit maakte het moeilijk om te bewijzen of bekende risicofactoren invloed hadden op het ontstaan van een tweede recidief. Mogelijk was er ook een selectie bias (patiënten werden niet willekeurig toegewezen aan een van de behandelingsmodaliteiten: PNF of SF), mogelijk veroorzaakte dit de gunstiger resultaten. Echter gezien het feit dat dit de eerste studie ooit is naar de effectiviteit en lange termijn resultaten van PNF, denken wij dat het toch de moeite waard is om te publiceren.

Definities

Zoals vermeld in alle hoofdstukken over de recidieven, is het begrip recidief slecht gedefinieerd waar het gaat om de ziekte van Dupuytren. Dit maakt een vergelijking met eerder gerapporteerde studies bijna onmogelijk. De meest gebruikte definitie is "terugkeer van de weefsels van Dupuytren in een eerder geopereerde zone" (McFarlane 1990, Becker 2010). Deze definitie van recidief kan niet worden gebruikt in dit onderzoek, omdat bij PNF geen weefsel wordt verwijderd. Noduli die aanwezig zijn voor de procedure blijven vaak onveranderd of worden op zijn best zachter. De strengen worden doorsneden, maar na verloop van tijd lijken deze opnieuw te verbinden. Voor deze studie is dan ook gebruik gemaakt van een meer indirecte, maar kwantitatieve defini-

tie voor herhaling: een verslechtering van het totale Passive Extensie Deficit (TPED) van 30º of meer in een straal ten opzichte van het resultaat 6 weken na de behandeling. Deze definitie is reproduceerbaar en klinisch relevanter dan de andere definities, want het is de progressie van de contractuur die uiteindelijk leidt tot functionele problemen en tot het verzoek om een reïnterventie uit te voeren, terwijl de terugkeer van het weefsel van Dupuytren niet noodzakelijk de handfunctie nadelig beïnvloedt, noch de indicatie voor behandeling is. Gekozen is voor een verslechtering van 30 º, omdat dit overeenkomt met Hueston's tabletoptest en omdat het de minimale contractuur is waarbij een patiënt in aanmerking komt voor een operatie in ons behandelcentrum.

In de studies betreffende de werkzaamheid van Clostridium Histolyticum afgeleid Collagenase, die net als onze studies werden ontworpen in de laatste tien jaar, werden andere indicaties voor behandeling (contractuur van> 20˚), resultaten en recidief gebruikt (Hurst 2009, Watt 2010, Gilpin 2010). Omdat het FDA-goedgekeurde protocol alleen toegestaan was voor de behandeling van een gewricht, werden de effecten hiervan ook per gewricht vermeld en niet per straal zoals in onze studies. De auteurs beschouwen een behandeling als "klinisch succesvol" als de correctie van de afwijking binnen 0-5˚ van volledige extensie was. Dit is in wetenschappelijke zin een waardevolle aanvulling op de defintitie die in onze studies werd gebruikt, het reductiepercentage voor een complete straal. Echter, een succesvolle behandeling in een MCP gewricht is op geen enkele wijze een succesvolle behandeling van de hele straal, laat staan van de hele hand: een afwijkende stand van andere gewrichten in de hand kan de functie van de hand nog fors beperken, en de handfunctie is hetgeen het succes van de behandeling van de ziekte van Dupuytren bepaalt. Daarom zijn wij van mening dat men niet alleen resultaten dient te rapporteren per gewricht, maar ook voor een complete straal en de gehele hand.

Daarnaast worden in studies over recidief na behandeling met collagenase, alleen de met "klinisch succes" behandelde gewrichten vervolgd bij het analyseren van het recidiefpercentage (Hurst 2009, Watt 2010, Xiaflex persbericht 2011). Dit is een misleidende manier van datapresentatie. In recent gepubliceerde gegevens over de werkzaamheid van Collagenase bijvoorbeeld, bereikten slechts 623 van de 1568 behandelde gewrichten klinisch succes (39,7%), en bereikten dus 945 deze uitkomstmaat niet. Na 3 jaar, was er sprake van recidief in 217 gewrichten, gedefinieerd als een toename van

de PED van ten minste 20˚. Dit komt overeen met een recidiefpercentage van 34,8% (217/623), terwijl het recidiefpercentage van de andere subgroep onbekend is, wat uiteraard zorgt voor een bias.

In de voorliggende studie vielen alle behandelde stralen van één hand uit de studie wanneer er in één van deze stralen zich een recidief voordeed. Achteraf was het misschien beter geweest de overige stralen te vervolgen.

De thema's over definities van de succesvolle behandeling en recidief gaven ons zo veel stof tot nadenken, dat wij samen met twee Amerikaanse collega's, Drs Denkler en Drs Pess uit de collagenase werkgroep besloten om een systematische review over het onderwerp te schrijven. Deze review werd uitgevoerd in januari 2010 en daarmee konden wij onze eigen vijf jaars resultaten, hoewel voor ons zelf reeds beschikbaar, niet opnemen in de resultaten. Het combineren van de resultaten van deze systematische review met onze eigen ervaring leidt tot de volgende adviezen voor toekomstig onderzoek:

TOEKOMSTPERSPECTIEVEN

Idealiter zouden interventies voor de ziekte van Dupuytren moeten worden onderzocht in grootschalige, gerandomiseerde, dubbelblinde, gecontroleerde klinische studies met goed gedefinieerde patiëntenpopulaties en tijdstippen voor de evaluatie. Als randomisatie onmogelijk of onpraktisch is, moeten grote cohorten worden gebruikt, zodat gematcht kan worden op patiëntkenmerken en de ernst van de contractuur. Met alle diathesekenmerken moet rekening worden gehouden, evenals met bijkomende ziekten zoals diabetes mellitus en lever-en vaatziekten, en omgevingsfactoren, zoals roken, alcoholgebruik en blootstelling aan trillingen (Descatha 2011).

Dubbele blindering is bijna onmogelijk in studies die chirurgische ingrepen vergelijken. Blinderen van de onderzoeker die de follow-up uitvoert kan worden bereikt door het gebruik van niet-transparante, nauwsluitende handschoenen.

Wanneer elke studie dezelfde definitie van recidief zou gebruiken, die van toepassing zou zijn op iedere behandelingsmodaliteit, zou vergelijking tussen verschillende inter-

venties mogelijk zijn. De volgende definitie van recidief is aan te raden: een toename van de TPED van een vast aantal graden (20 of 30°) in vergelijking met de directe postoperatieve metingen in de behandelde straal. Extensie moet worden gedefinieerd als een toename van 20-30° TPED in een straal buiten het behandelde gebied. Op deze manier zijn zowel recidief als extensie klinisch relevant voor de patiënt, daar de handfunctie verslechtert wanneer Hueston's tabletoptest positief is. Bovendien moeten de goniometrische waarden van elk gewricht worden opgenomen in een database om vergelijking tussen verschillende studies mogelijk te maken. Follow-up onderzoek dient plaats te vinden op vaste tijdstippen en bij voorkeur op de termijn van één week, 4-6 weken, 6 maanden en jaarlijks tot ten minste vijf jaar na de behandeling.

Vele nieuwe veelbelovende technieken zijn momenteel in ontwikkeling bij de behandeling van de ziekte van Dupuytren. Zeer recent werd een onderzoek gepubliceerd waarbij uitgebreide percutane aponeurotomie verricht werd in combinatie met lipografting (Hovius 2011). De auteurs vonden de resultaten van de reguliere aponeurotomie teleurstellend en voegden vet subcutaan toe, als interpositie tussen de huid en fascia, maar ook om het relatieve tekort aan onderhuids vet te herstellen. Korte termijn resultaten zijn veelbelovend: bij 50 patiënten die werden behandeld, varieerde de gemiddelde verbetering van 56,4% tot 114%, en 88% van de patiënten bereikte Tubiana stadium I na de behandeling. De lange termijn resultaten zijn op dit moment nog niet beschikbaar.

Ook worden vele studies uitgevoerd naar de behandeling met collagenase (Badalamente 2000, 2002, 2007, Hurst 2009, Watt 2010). Het zou interessant zijn om collagenase te vergelijken met andere behandelingen van de ziekte van Dupuytren om te zien of dit echt een goed alternatief is. In de nabije toekomst zullen meer gegevens beschikbaar komen met betrekking tot de lange termijn resultaten en de effectiviteit.

In Duitsland wordt door sommigen radiotherapie toegepast bij een vroeg stadium van Dupuytren (Betz 2010).

Er moet echter meer onderzoek worden gedaan, niet alleen op effectiviteit en veiligheid van deze technieken, maar nog belangrijker, om de resultaten van deze behandelingen te vergelijken bij gelijke groepen op een gerandomiseerde, gecontroleerde manier.

In deze studie is voor het eerst aangetoond dat een hogere leeftijd ten tijde van de behandeling het risico op recidief vermindert. Het zou interessant zijn om te zien of dit opnieuw kan worden bevestigd in grotere studies, en om te zien of er een ander advies over de behandeling moet worden gegeven aan verschillende leeftijdsgroepen.

Een andere onbeantwoorde vraag blijft wat de rol is van de postoperatieve hand- en spalktherapie bij de behandeling van Dupuytren. Hoewel het routinematig spalken na fasciectomie en dermatofaciectomie de range of motion en de functie niet lijkt te verbeteren, is er mogelijk plaats voor spalken na de minder invasieve behandelingen, zoals PNF, collagenase, of radiotherapie (Meinel, 2011, Jerosch-Herold 2011).

Last but not least, is er zeer weinig literatuur beschikbaar over de behandeling van recidieven, onafhankelijk welke techniek wordt gebruikt. Recidieven komen zeer vaak voor, ongeacht welke initiële behandelingsmodaliteit wordt gebruikt. Het zou heel interessant zijn om te onderzoeken welke behandeling superieur is bij de behandeling van een recidief, of de verschillende leeftijdsgroepen andere resultaten hebben na de behandeling voor het recidief en of spalken of handtherapie van enig nut zijn na de behandeling van het recidief.

We hebben aangetoond dat PNF een waardig alternatief is bij de behandeling van recidieven. Verder onderzoek met grotere groepen patiënten is nodig om de specifieke indicaties te definiëren. En hopelijk zullen we in de toekomst in staat zijn om de resultaten van PNF met andere behandelingen voor recidieven te vergelijken. Dit kan alleen gedaan worden als gestandaardiseerd en goed beschreven definities voor recidief en de resultaten van de behandelingen worden gebruikt.

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DANKWOORD (ACKNOWLEDGEMENTS)

Natuurlijk wil ik graag van de gelegenheid gebruikmaken om iedereen die heeft bijgedragen aan het tot stand komen van dit boekje te bedanken.

Prof. Dr. P.M.N. Werker, beste Paul, ik weet dat ik je heel erg vaak tot wanhoop heb gedreven! Vaak geloofde ik zelf ook niet dat het ooit nog af zou komen, maar dankzij jouw niet aflatende enthousiasme ben ik toch doorgegaan. Ik had mij geen betere, meer motiverende promotor kunnen wensen. Toen het einde in zicht kwam volgde nog even de allergrootste hobbel, maar ook daar heb je mij overheen geholpen. Ik ben het onderzoek doen steeds meer gaan waarderen en ik hoop dat we in de toekomst samen onderzoek zullen blijven doen.

Drs. H. Ter Linden, beste Hein, jij mag natuurlijk ook niet ontbreken, aangezien jij een groot deel van de behandelingen en follow-up voor je rekening hebt genomen, en hoofdleverancier van de illustraties bent in dit proefschrift. Heel erg bedankt!

Isala Research afdeling, met name Helen Klip en Boudewijn Kollen, die beiden helaas niet meer werkzaam zijn op deze afdeling: dank zij jullie hulp heb ik statistische analyses, en het werken met SPSS enigszins onder de knie gekregen. Heel hartelijk dank voor jullie hulp!

Marieke Dreise en Nicolien Wieringa, beiden heel erg bedankt voor jullie kritische blik en correcties van het Engels.

Maatschap Plastische Chirurgie Isala Klinieken Zwolle, beste Jeroen, Marieke, Max, Michiel en Peter, heel erg bedankt dat jullie mij in jullie tijd hebben laten werken aan dit promotieonderzoek. Ik kijk er ontzettend naar uit om vanaf 1 juli onderdeel uit te mogen maken van de maatschap, waar ik in de afgelopen jaren ontzettend veel van heb geleerd en heel veel respect en bewondering voor heb opgebouwd. Ik hoop dat ik een waardevolle aanvulling zal zijn en nog vele jaren met jullie samen mag werken.

Secretariaat Plastische Chirurgie Isala Klinieken, Zwolle, beste Anja's, Esther, Jolanda, José, Selda, Susanne, Tamara en Wendy. Dank zij jullie, en met name dank zij Susanne en haar controle lijst, zijn alle patiënten op tijd gezien gedurende de gehele studie en is de uitval zo laag. Bovendien heb ik jaren vele planken op het secretariaat mogen bezetten en in de beginjaren zelfs vaak een van jullie werkplekken. Het was ook nog eens gezellig. Bedankt!

Paranimfen: Lieve Tallechien en Narda, naast collega's zijn jullie ook allebei goede vrienden geworden. Heel erg fijn dat jullie mij bij willen staan tijdens mij promotie en mijn paranimfen willen zijn!!

Lieve Roos, wat fantastisch dat ik werkelijk met ALLES bij jou kan aankloppen. En dat dit proefschrift er zo uitziet zoals het eruit ziet is volledig aan jou te danken.

Lieve Wouter, dank je wel voor het lezen van ook de punten en komma's: dankzij jou zijn op de valreep een hoop van mijn slordigheden verdwenen in de definitieve druk!

Een proefschrift komt niet tot stand zonder emotionele steun. Van familie, schoonfamilie en vrienden heb ik gedurende vele jaren deze steun mogen ontvangen. Hen wil ik daarvoor uitvoerig dankzeggen! Twee wil ik daarbij met name noemen:

Lieve mama, dank je wel voor alle steun, natuurlijk niet alleen tijdens mijn promotie maar ook ervoor. Jou ben ik het meest dankbaar omdat ik door jou ben geworden, wie ik ben!

Lieve Dennis, dat we maar samen oud mogen worden met onze kleine Kokkies!

List of publications

A comparison of the direct outcomes of percutaneous needle fasciotomy and limited fasciectomy for Dupuytren's disease: a 6-week follow-up study. Van Rijssen AL, Gerbrandy FS, Ter Linden H, Klip H, Werker PM. J Hand Surg Am. 2006 May-Jun;31(5):717-25.

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